Phebra Pty Ltd 19 Orion Road, Lane Cove West NSW 2066 Australia Locked Bag 3003, Hunters Hill NSW 2110 Australia T +61 (0]2 9420 9199 F +61 (0]2 9420 9177 W www.phebra.com

ACN: 059 357 890 ABN: 77 695 661 635



DigiFab®

Phebra Pty Ltd

Chemwatch: 4777-06

Version No: 2.1.1.1 Material Safety Data Sheet according to NOHSC and ADG requirements

Chemwatch Hazard Alert Code: 2

Issue Date: 27/06/2017 Print Date: 07/03/2018 S.Local.AUS.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

Product name	DigiFab®
Synonyms	Not Available
Other means of identification	Not Available
Relevant identified uses of the substance or mixture and uses advised against	

Relevant identified uses DigiFab® is indicated for the treatment of patients with life-threatening or potentially life-threatening digoxin toxicity or overdose. Although designed specifically to treat digoxin overdose, a product very similar to DigiFab® (Digibind) has been used successfully to treat life-threatening digitoxin overdose. Since human experience is limited, and the consequences of repeated exposure are unknown, DigiFab® is not indicated for milder cases of digitalis toxicity.

Details of the supplier of the safety data sheet

Registered company name	Phebra
Address	19 Orion Road Lane Cove West NSW 2066 Australia
Telephone	+61 2 9420 9199 1800 720 020
Fax	+61 2 9420 9177
Website	www.phebra.com
Email	info@phebra.com

Emergency telephone number

<u> </u>	
Association / Organisation	Not Available
Emergency telephone numbers	+61 401 264 004
Other emergency telephone numbers	N/A

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to NOHSC Criteria, and ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max	
Flammability	1		
Toxicity	0		0 = Minimum
Body Contact	2		1 = Low
Reactivity	1		3 = High
Chronic	0		4 = Extreme

Poisons Schedule	Not Applicable
Risk Phrases ^[1]	Not Applicable
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Not Applicable

Relevant risk statements are found in section 2

Indication(s) of danger Not Applicable

SAFETY ADVICE

Not Applicable

Other hazards

Cumulative effects may result following exposure*.

May produce discomfort of the eyes, respiratory tract and skin*.

Possible respiratory and skin sensitizer*.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
127-09-3	64.1	sodium acetate, anhydrous
Not Available	34.2	affinity purified specific anti-digoxin ovine fab
69-65-8	1.7	mannitol

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	 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.
Skin Contact	 If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Ingestion	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

- Water spray or fog.
- ▶ Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
Advice for firefighters	
Fire Fighting	 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. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
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). 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. In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is often called the "Minimum Explosible Concentration", MEC). When processed with flammable liquids/vapors/mists,ignitable (hybrid) mixtures may be formed with combustible dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture will be lower than the individual LELs for the vapors/mists or dusts. Combustion products include: , carbon monoxide (CO) , carbon monoxide (CO)

	, hydrogen cyanide , other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Minor Spills	 Clean up all spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Sweep up, shovel up or Vacuum up (consider explosion-proof machines designed to be grounded during storage and use). Place spilled material in clean, dry, sealable, labelled container.
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. Prevent, by any means available, spillage from entering drains or water courses. Recover product wherever possible. IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe 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. DO NOT enter confined spaces until atmosphere has been checked. DO NOT enter confined spaces until atmosphere has been checked. DO NOT enter confined spaces until atmosphere has been checked. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. 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. Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area. Do not use air hoses for cleaning.
Other information	 Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS. For major quantities: Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams). Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities. [Store Digifab® refrigerated at 2 to 8°C (36 to 46°F). Do not freeze.

Conditions for safe storage, including any incompatibilities

Suitable container	 Glass container is suitable for laboratory quantities Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)	
INGREDIENT DATA	
Not Available	

EMERGENCY LIMITS

Ingredient

TEEL-1

TEEL-2

TEEL-3

sodium acetate, anhydrous	Sodium acetate	11 mg	ı/m3	120 mg/m3	700 mg/m3
mannitol	Hexanehexol, 1,2,3,4,5,6-; (Mannitol)	120 m	ng/m3	1,400 mg/m3	2,700 mg/m3
Ingredient	Original IDLH		Revised IDLH		
sodium acetate, anhydrous	Not Available		Not Available		
affinity purified specific anti-digoxin ovine fab	Not Available		Not Available		
mannitol	Not Available		Not Available		

Exposure controls

Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure. • Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
Personal protection	
Eye and face protection	 Safety glasses with side shields. Chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly.
Skin protection	See Hand protection below
Hands/feet protection	 NOTE: The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. 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 can not 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. Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried throughly. Application of a non-perfumed moisturizer is recommended. Suitability and durability of glove type is dependent on usage. 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. butyl rubber. fluorocaoutchouc. polyvinyl chloride. Gloves should be examined for wear and/ or degradation constantly.
Body protection	See Other protection below
Other protection	 Overalls. P.V.C. apron. Barrier cream. Skin cleansing cream. Eye wash unit.
Thermal hazards	Not Available

Respiratory protection

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

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

* - Negative pressure demand ** - Continuous flow

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

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chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 deqC)

- 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

Information on basic physical and chemical properties

Appearance DigiFab® is a solid white to off white powder; mixes with water.

Physical state	Divided Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	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 in excessive exposures. There is some evidence to suggest that the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.
Skin Contact	Open cuts, abraded or irritated skin should not be exposed to this material There is some evidence to suggest that the material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering.
Eye	Limited evidence or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn).
Chronic	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population. There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

	Long term exposure to high dust concentrations may cause changes in lur penetrating and remaining in the lung. Dusts produced by proteins can sometimes sensitise workers like other for wheezing, narrowing of the airways and breathing difficulties.	ng function i.e. pneumo eign bodies. Symptoms	coniosis, caused by particles less than 0.5 micron sinclude asthma appearing soon after exposure, with
	ΤΟΧΙΟΙΤΥ	IRRITATION	
DigiFab®	Not Available	Not Available	
	тохісіту	IRRITATION	
sodium acetate, anhydrous	Oral (rat) LD50: 3530 mg/kg ^[2]	Eye (rabbit): 10 r	mg - mild
		Skin (rabbit): 550	0 mg/24h - mild
	тохісіту	IRRITATION	
mannitol	Oral (rat) LD50: 13500 mg/kg ^[2]	Not Available	
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute tox data extracted from RTECS - Register of Toxic Effect of chemical Substan	city 2.* Value obtained aces	from manufacturer's SDS. Unless otherwise specified
DigiFab®	The material may be irritating to the eye, with prolonged contact causing in conjunctivitis. The material may cause skin irritation after prolonged or repeated exposur scaling and thickening of the skin. Asthma-like symptoms may continue for months or even years after expose reactive airways dysfunction syndrome (RADS) which can occur after exp RADS include the absence of previous airways disease in a non-atopic ind hours of a documented exposure to the irritant. Other criteria for diagnosis severe bronchial hyperreactivity on methacholine challenge testing, and th asthma) following an irritating inhalation is an infrequent disorder with rate substance. On the other hand, industrial bronchitis is a disorder that occu particles) and is completely reversible after exposure ceases. The disorder	flammation. Repeated e and may produce on ure to the material ends ossure to high levels of ividual, with sudden on s of RADS include a re- e lack of minimal lympt is related to the concer rs as a result of expos. r is characterized by di	or prolonged exposure to irritants may produce contact skin redness, swelling, the production of vesicles, . This may be due to a non-allergic condition known as highly irritating compound. Main criteria for diagnosing uset of persistent asthma-like symptoms within minutes to versible airflow pattern on lung function tests, moderate to nocytic inflammation, without eosinophilia. RADS (or ntration of and duration of exposure to the irritating ure due to high concentrations of irritating substance (often ifficulty breathing, cough and mucus production.
Acute Toxicity	0	Carcinogenicity	0
Skin Irritation/Corrosion	\odot	Reproductivity	\odot
Serious Eye Damage/Irritation	STO STO	- Single Exposure	\odot
Respiratory or Skin sensitisation	Stot-1	Repeated Exposure	\otimes
Mutagenicity	0	Aspiration Hazard	0
		Legend: 🗙 –	Data available but does not fill the criteria for classification Data available to make classification

S – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
Not Available	Not Available	Not Available	Not Available	Not Available
ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
LC50	96	Fish	>=100mg/L	1
EC50	48	Crustacea	>385.3mg/L	2
ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
Not Available	Not Available	Not Available	Not Available	Not Available
	ENDPOINT Not Available ENDPOINT LC50 EC50 ENDPOINT Not Available	ENDPOINT TEST DURATION (HR) Not Available Not Available ENDPOINT TEST DURATION (HR) LC50 96 EC50 48 ENDPOINT TEST DURATION (HR) Not Available Not Available	ENDPOINTTEST DURATION (HR)SPECIESNot AvailableNot AvailableNot AvailableENDPOINTTEST DURATION (HR)SPECIESLC5096FishEC5048CrustaceaENDPOINTTEST DURATION (HR)SPECIESNot AvailableNot AvailableNot Available	ENDPOINTTEST DURATION (HR)SPECIESVALUENot AvailableNot AvailableNot AvailableNot AvailableENDPOINTTEST DURATION (HR)SPECIESVALUELC5096Fish>=100mg/LEC5048Crustacea>385.3mg/LENDPOINTTEST DURATION (HR)SPECIESVALUENot AvailableNot AvailableNot AvailableNot Available

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity Data 2. EUrope ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

Proteins are generally easily biodegradable.

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
sodium acetate, anhydrous	LOW	LOW
mannitol	LOW	LOW

Ingredient	Bioaccumulation
sodium acetate, anhydrous	HIGH (BCF = 29100)
mannitol	LOW (LogKOW = -3.0108)
Mobility in soil	

Ingredient	Mobility
sodium acetate, anhydrous	HIGH (KOC = 1)
mannitol	LOW (KOC = 10)

SECTION 13 DISPOSAL CONSIDERATIONS

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. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted. • 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. • 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.
	 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

Labels Required

· · · · · · · · · · · · · · · · · · ·	
Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADG): 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

SECTION 15 REGULATORY INFORMATION

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

SODIUM ACETATE, ANHYDROUS(127-09-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

MANNITOL(69-65-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (mannitol; sodium acetate, anhydrous)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Υ

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 OTHER INFORMATION

Other information

Ingredients with multiple cas numbers

Name	CAS No
mannitol	69-65-8, 87-78-5

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC — TWA: Permissible Concentration-Time Weighted Average PC — STEL: Permissible Concentration-Short Term Exposure Limit IARC: International Agency for Research on Cancer ACGIH: American Conference of Governmental Industrial Hygienists STEL: Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit_o IDLH: Immediately Dangerous to Life or Health Concentrations OSF: Odour Safety Factor NOAEL : No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level LOXEL: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index

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