



Pepsin Solution

Leica Biosystems Amsterdam

Version No: 1.5
Safety Data Sheet (Conforms to Regulations (EC) No 453/2010)

Chemwatch Hazard Alert Code: 0

Issue Date: 05/22/2015
Print Date: 05/27/2015
Initial Date: 05/11/2015
L.REACH.NLD.EN

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

1.1. Product Identifier

Product name	Pepsin Solution
Synonyms	LK-101x
Other means of identification	Not Available

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

Relevant identified uses	Part of pretreatment kits
Uses advised against	Not Applicable

1.3. Details of the manufacturer/importer

Registered company name	Leica Biosystems Amsterdam
Address	Vlierweg 20 Amsterdam Netherlands
Telephone	0031-20 6919181
Fax	0031-20 6963531
Website	www.leicabiosystems.com
Email	info.amsterdam@leicabiosystems.com

1.4. Emergency telephone number

Association / Organisation	Leica Biosystems Amsterdam
Emergency telephone numbers	0031-20 6919181
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

DSD classification	In case of mixtures, classification has been prepared by following DPD (Directive 1999/45/EC) and CLP Regulation (EC) No 1272/2008 regulations
DPD classification	Not Applicable
Classification according to regulation (EC) No 1272/2008 [CLP] [1]	Not Applicable

2.2. Label elements

CLP label elements	Not Applicable
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SIGNAL WORD **NOT APPLICABLE**

Hazard statement(s)

Not Applicable

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Precautionary statement(s) Prevention

Precautionary statement(s) Response

Precautionary statement(s) Storage

Precautionary statement(s) Disposal

2.3. Other hazards

Possible respiratory sensitizer*.

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

1.CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to directive 67/548/EEC [DSD]	Classification according to regulation (EC) No 1272/2008 [CLP]
1.7732-18-5 2.231-791-2 3.Not Available 4.Not Available	98-100	<u>water</u>	Not Applicable	Not Applicable
1.9001-75-6 2.232-629-3 3.647-008-00-6 4.Not Available	<1	<u>pepsin</u>	R36/37/38R42 [2]	Eye Irrit. 2, STOT SE 3, Skin Irrit. 2, Resp. Sens. 1; H319, H335, H315, H334 [3]
1.26628-22-8 2.247-852-1 3.011-004-00-7 4.01-2119457019-37-XXXX	<.1	<u>sodium azide</u>	R28R32R50/53 [2]	Acute Tox. 2 *, Aquatic Acute 1, Aquatic Chronic 1; H300, H400, H410, EUH032 [3]

Legend:

1. Classified by Chemwatch; 2. Classification drawn from EC Directive 67/548/EEC - Annex I; 3. Classification drawn from EC Directive 1272/2008 - Annex VI
4. Classification drawn from C&L

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 FIRST AID MEASURES

4.1. Description of first aid measures

General	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary. <p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with water. ▶ If irritation continues, seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. <p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Eye Contact	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with water. ▶ If irritation continues, seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

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

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

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5.1. Extinguishing media

	<ul style="list-style-type: none"> ▶ There is no restriction on the type of extinguisher which may be used. ▶ Use extinguishing media suitable for surrounding area.
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5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
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5.3. Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding 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	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. Decomposition may produce toxic fumes of; hydrogen cyanide nitrogen oxides (NOx)

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

	See section 8
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6.2. Environmental precautions

	See section 12
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6.3. Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment. ▶ Contain and absorb spill with sand, earth, inert material or vermiculite. ▶ Wipe up. ▶ Place in a suitable, labelled container for waste disposal.
Major Spills	Not Applicable

6.4. Reference to other sections

	Personal Protective Equipment advice is contained in Section 8 of the MSDS.
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SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this MSDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Fire and explosion protection	See section 5
Other information	Not Applicable

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Avoid contamination of water, foodstuffs, feed or seed. It is suggested that crystalline proteins are explosive as evidenced by the easily induced shattering of microcrystals. This may be a consequence of the implosive collapse of a metastable ordering of molecules (Bretherick's Handbook of Reactive Chemical Hazards).

PACKAGE MATERIAL INCOMPATIBILITIES

Not Available

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7.3. Specific end use(s)

See section 1.2

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1. Control parameters****DERIVED NO EFFECT LEVEL (DNEL)**

Not Available

PREDICTED NO EFFECT LEVEL (PNEC)

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)**INGREDIENT DATA**

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (English)	sodium azide	Sodium azide	0,1 mg/m3	0,3 mg/m3	Not Available	Skin
EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs)	sodium azide	Sodium azide	0.1 mg/m3	0.3 mg/m3	Not Available	Skin
Netherlands Occupational Exposure Limits (Dutch)	sodium azide	Natriumazide	0,1 mg/m3	0,3 mg/m3	Not Available	Table A: Lijst met wettelijke grenswaarden

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
sodium azide	Sodium azide	1.8 mg/m3	20 mg/m3	32 mg/m3

Ingredient	Original IDLH	Revised IDLH
water	Not Available	Not Available
pepsin	Not Available	Not Available
sodium azide	Not Available	Not Available

MATERIAL DATA

CEL Ceiling: 0.00006 mg/m3 (sensitiser)

(compare TLV-C subtilisins; proteolytic enzymes - 100% crystalline)

Exposure at or below the recommended TLV-C is thought to minimise the potential for allergic respiratory sensitization for the majority of immunologically normal persons and to minimise skin irritation and sensitization. TLV compliance is contingent on measurement of workplace air concentrations with a high volume sampler appropriate to capture these proteins for at least 60 minutes. Although the recommended TLV-C is specifically prescribed for subtilisins, the Chemwatch recommendation (CEL) recognizes that all proteins have the potential to produce allergic responses. It should be noted, however, that proteins are typically poorly absorbed through the skin and after inhalation. Literature reports indicate that protein bioavailability, via the lung, is as low as 2% for sodium azide:

Deaths due to sodium azide exposure are due to acute cardiovascular collapse, and central respiratory paralysis. Inhalation (or ingestion) produces dizziness, weakness, blurred vision, slight dyspnea, tachypnea, hypotension, tachycardia, acidosis, abdominal pain and spasms. Serious exposures produce polydipsia, leukocytosis, pulmonary oedema, bronchitis, convulsions, unconsciousness, and death. Solutions of sodium azide release hydrazoic acid which has the same degree of acute toxicity as the salt.

Exposures must be controlled to very low levels to avoid hypotension.

Estimation of a maximal intake of sodium azide over an 8-hour shift (assuming 10 m3 of air inhaled and a 75% retention) for a daily pulmonary absorption of 0.75 mg results in an ambient air concentration of 0.04 ppm (0.1 mg/m3). The permissible limits of exposure to both sodium and hydrogen azides are thought to incorporate a reasonable margin of safety against headache and other symptoms of systemic discomfort and are thought to be protective against significant changes in electrocardiogram readings and hypotension. An alert has been published by OSHA to highlight the fact that significant percutaneous absorption may occur and this route may contribute significantly to worker exposure.

8.2. Exposure controls**8.2.1. 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.

General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)

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	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)
	Within each range the appropriate value depends on:	
	Lower end of the range	Upper end of the range
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
	2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
	3: Intermittent, low production.	3: High production, heavy use
	4: Large hood or large air mass in motion	4: Small hood - local control only
	Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.	
8.2.2. Personal protection		
Eye and face protection	<ul style="list-style-type: none"> ▶ 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. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent] 	
Skin protection	See Hand protection below	
Hands/feet protection	<p>Wear general protective gloves, eg. light weight rubber gloves.</p> <p>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.</p> <p>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.</p> <p>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:</p> <ul style="list-style-type: none"> ▶ frequency and duration of contact, ▶ chemical resistance of glove material, ▶ glove thickness and ▶ dexterity <p>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).</p> <ul style="list-style-type: none"> ▶ When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. ▶ When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. ▶ Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use. ▶ Contaminated gloves should be replaced. <p>Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p>	
Body protection	See Other protection below	
Other protection	No special equipment needed when handling small quantities.	
Thermal hazards	Not Available	

Respiratory protection

Type B-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

8.2.3. Environmental exposure controls

See section 12

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Liquid	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

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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 Available
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 Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

9.2. Other information

	Not Available
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SECTION 10 STABILITY AND REACTIVITY

10.1.Reactivity	See section 7.2
10.2.Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product
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. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	The liquid may be miscible with fats or oils and may degrease the skin, producing a skin reaction described as non-allergic contact dermatitis. The material is unlikely to produce an irritant dermatitis as described in EC Directives .
Eye	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. There is a possibility that unintended contact with this product (such as through a cut, needle stick, eye or mucous membrane, or inhalation) could result in allergic or hypersensitivity reactions. Such reactions are more likely following repeated exposures or in persons with a pre-existing allergy to certain proteins. Dusts produced by proteins are capable, under certain conditions, of sensitising workers by virtue of the bodies reaction to foreign proteins. Typical allergic asthma may be rapidly produced after exposure, with symptoms may include chronic cough, sputum production, fever, myalgia, fatigue, airway obstruction; chest radiographs may show a generalised reticulonodular pattern, or basal or apical fibrosis. In addition there may be retrosternal discomfort, headache, stomach-ache and general severe dyspnoea may develop giving a clinical picture similar to that of farmer's lung and allied conditions of extrinsic allergic alveolitis. No irritation is likely after brief skin contact, but prolonged contact in the presence of moisture may result in soreness, redness, inflammation and possible ulceration of the skin. Repeated attacks may lead to permanent impairment of lung function due to fibrotic change.

Pepsin Solution	TOXICITY	IRRITATION
	Not Available	Not Available
water	TOXICITY	IRRITATION
	Oral (rat) LD50: >90000 mg/kg ^[2]	Not Available
pepsin	TOXICITY	IRRITATION
	Not Available	Not Available

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sodium azide	TOXICITY	IRRITATION
	dermal (rat) LD50: 50 mg/kg ^[2]	Not Available
	Oral (rat) LD50: 27 mg/kg ^[2]	
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's msds. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

Pepsin Solution	<p>No significant acute toxicological data identified in literature search.</p> <p>Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive. Factors which increase the sensitivity of the mucosa may play a role in predisposing a person to allergy. They may be genetically determined or acquired, for example, during infections or exposure to irritant substances. Immunologically the low molecular weight substances become complete allergens in the organism either by binding to peptides or proteins (haptens) or after metabolism (prohaptens). Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis.</p>
WATER	No significant acute toxicological data identified in literature search.
PEPSIN	<p>Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.</p> <p>Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive. Factors which increase the sensitivity of the mucosa may play a role in predisposing a person to allergy. They may be genetically determined or acquired, for example, during infections or exposure to irritant substances. Immunologically the low molecular weight substances become complete allergens in the organism either by binding to peptides or proteins (haptens) or after metabolism (prohaptens). Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure. No significant acute toxicological data identified in literature search.</p>
SODIUM AZIDE	General anaesthesia, somnolence, convulsions, headache, irritability, arrhythmias, dyspnae, respiratory stimulation, diarrhoea recorded.

Acute Toxicity	☹	Carcinogenicity	☹
Skin Irritation/Corrosion	☹	Reproductivity	☹
Serious Eye Damage/Irritation	☹	STOT - Single Exposure	☹
Respiratory or Skin sensitisation	☹	STOT - Repeated Exposure	☹
Mutagenicity	☹	Aspiration Hazard	☹

Legend: ✔ – Data required to make classification available
✘ – Data available but does not fill the criteria for classification
☹ – Data Not Available to make classification

CMR STATUS

SKIN	sodium azide	European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) - Skin	Skin
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SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

NOT AVAILABLE

Ingredient	Endpoint	Test Duration	Effect	Value	Species	BCF
water	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
pepsin	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
sodium azide	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

Proteins are generally easily biodegradable.

12.2. Persistence and degradability

Continued...

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Ingredient	Persistence: Water/Soil	Persistence: Air
water	LOW	LOW
sodium azide	LOW	LOW

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
water	LOW (LogKOW = -1.38)
sodium azide	LOW (LogKOW = 0.1631)

12.4. Mobility in soil

Ingredient	Mobility
water	LOW (KOC = 14.3)
sodium azide	HIGH (KOC = 1.342)

12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT and vPvB Criteria fulfilled?	Not Available	Not Available	Not Available

12.6. Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product / Packaging disposal	<p>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.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. 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.</p> <ul style="list-style-type: none"> ▶ 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. ▶ Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or incineration in a licenced apparatus (after admixture with suitable combustible material). ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
	Waste treatment options
Sewage disposal options	Not Available

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
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Land transport (Not Applicable): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. Packing group	Not Applicable	
14.3. UN proper shipping name	Not Applicable	
14.4. Environmental hazard	No relevant data	
14.5. Transport hazard class(es)	Class	Not Applicable
	Subrisk	Not Applicable
14.6. Special precautions for user	Hazard identification (Kemler)	Not Applicable
	Classification code	Not Applicable

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Hazard Label	Not Applicable
Special provisions	Not Applicable
Explosive Limit and Limited Quantity Index	Not Applicable
ERAP Index	Not Applicable
Limited quantity	Not Applicable

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

14.1. UN number	Not Applicable															
14.2. Packing group	Not Applicable															
14.3. UN proper shipping name	Not Applicable															
14.4. Environmental hazard	No relevant data															
14.5. Transport hazard class(es)	<table border="1"> <tr> <td>ICAO/IATA Class</td> <td>Not Applicable</td> </tr> <tr> <td>ICAO / IATA Subrisk</td> <td>Not Applicable</td> </tr> <tr> <td>ERG Code</td> <td>Not Applicable</td> </tr> </table>		ICAO/IATA Class	Not Applicable	ICAO / IATA Subrisk	Not Applicable	ERG Code	Not Applicable								
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14.6. Special precautions for user	<table border="1"> <tr> <td>Special provisions</td> <td>Not Applicable</td> </tr> <tr> <td>Cargo Only Packing Instructions</td> <td>Not Applicable</td> </tr> <tr> <td>Cargo Only Maximum Qty / Pack</td> <td>Not Applicable</td> </tr> <tr> <td>Passenger and Cargo Packing Instructions</td> <td>Not Applicable</td> </tr> <tr> <td>Passenger and Cargo Maximum Qty / Pack</td> <td>Not Applicable</td> </tr> <tr> <td>Passenger and Cargo Limited Quantity Packing Instructions</td> <td>Not Applicable</td> </tr> <tr> <td>Passenger and Cargo Limited Maximum Qty / Pack</td> <td>Not Applicable</td> </tr> </table>		Special provisions	Not Applicable	Cargo Only Packing Instructions	Not Applicable	Cargo Only Maximum Qty / Pack	Not Applicable	Passenger and Cargo Packing Instructions	Not Applicable	Passenger and Cargo Maximum Qty / Pack	Not Applicable	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable
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Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable															
Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable															

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

14.1. UN number	Not Applicable							
14.2. Packing group	Not Applicable							
14.3. UN proper shipping name	Not Applicable							
14.4. Environmental hazard	Not Applicable							
14.5. Transport hazard class(es)	<table border="1"> <tr> <td>IMDG Class</td> <td>Not Applicable</td> </tr> <tr> <td>IMDG Subrisk</td> <td>Not Applicable</td> </tr> </table>		IMDG Class	Not Applicable	IMDG Subrisk	Not Applicable		
IMDG Class	Not Applicable							
IMDG Subrisk	Not Applicable							
14.6. Special precautions for user	<table border="1"> <tr> <td>EMS Number</td> <td>Not Applicable</td> </tr> <tr> <td>Special provisions</td> <td>Not Applicable</td> </tr> <tr> <td>Limited Quantities</td> <td>Not Applicable</td> </tr> </table>		EMS Number	Not Applicable	Special provisions	Not Applicable	Limited Quantities	Not Applicable
EMS Number	Not Applicable							
Special provisions	Not Applicable							
Limited Quantities	Not Applicable							

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable									
14.2. Packing group	Not Applicable									
14.3. UN proper shipping name	Not Applicable									
14.4. Environmental hazard	No relevant data									
14.5. Transport hazard class(es)	<table border="1"> <tr> <td>Not Applicable</td> <td>Not Applicable</td> </tr> </table>		Not Applicable	Not Applicable						
Not Applicable	Not Applicable									
14.6. Special precautions for user	<table border="1"> <tr> <td>Classification code</td> <td>Not Applicable</td> </tr> <tr> <td>Limited quantity</td> <td>Not Applicable</td> </tr> <tr> <td>Equipment required</td> <td>Not Applicable</td> </tr> <tr> <td>Fire cones number</td> <td>Not Applicable</td> </tr> </table>		Classification code	Not Applicable	Limited quantity	Not Applicable	Equipment required	Not Applicable	Fire cones number	Not Applicable
Classification code	Not Applicable									
Limited quantity	Not Applicable									
Equipment required	Not Applicable									
Fire cones number	Not Applicable									

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

Not Applicable

Pepsin Solution

SECTION 15 REGULATORY INFORMATION

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

water(7732-18-5) is found on the following regulatory lists	"European Customs Inventory of Chemical Substances ECICS (English)", "European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)", "EU REACH Regulation (EC) No 1907/2006 - Annex IV - Exemptions from the Obligation to Register in Accordance with Article 2(7)(a) (English)"
pepsin(9001-75-6) is found on the following regulatory lists	"European Customs Inventory of Chemical Substances ECICS (English)", "European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)", "European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI", "European Union (EU) Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances - updated by ATP: 31"
sodium azide(26628-22-8) is found on the following regulatory lists	"EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Polish)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Slovenian)", "European Customs Inventory of Chemical Substances ECICS (English)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Slovak)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (French)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Lithuanian)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Swedish)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Danish)", "European Trade Union Confederation (ETUC) Priority List for REACH Authorisation", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Maltese)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Italian)", "European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Latvian)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (English)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Spanish)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (German)", "European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Finnish)", "European Union (EU) Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances - updated by ATP: 31", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Czech)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Hungarian)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Portuguese)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Romanian)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Greek)", "Netherlands Occupational Exposure Limits (Dutch)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Dutch)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Estonian)", "European Union (EU) First List of Indicative Occupational Exposure Limit Values (IOELVs) (Bulgarian)"

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : 67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Regulation (EU) No 453/2010, Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and their amendments as well as the following British legislation: - The Control of Substances Hazardous to Health Regulations (COSHH) 2002 - COSHH Essentials - The Management of Health and Safety at Work Regulations 1999

15.2. Chemical safety assessment

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (water; pepsin)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
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

Full text Risk and Hazard codes

H300	Fatal if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.
R36/37/38	Irritating to eyes, respiratory system and skin.
R42	May cause SENSITISATION by inhalation.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Other information

Pepsin Solution**DSD / DPD label elements**

Not Applicable

Relevant risk statements are found in section 2.1

Indication(s) of danger	
	Not Applicable

SAFETY ADVICE

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.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net

The (M)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.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

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