

# BIOSYSTEMS

# Kreatech FISH probe ROW

## Leica Biosystems Amsterdam

Version No: 0.10

Safety Data Sheet (Conforms to Regulations (EC) No 2015/830)

Issue Date: **10/15/2015** Print Date: **10/15/2015** Initial Date: **09/01/2015** S.REACH.NLD.EN

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

#### 1.1.Product Identifier

| Product name                     | Kreatech FISH probe ROW |  |
|----------------------------------|-------------------------|--|
| Synonyms                         | pKBI series             |  |
| Other means of<br>identification | Not Available           |  |

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

| Relevant identified uses    | Use according to manufacturer's directions.     |  |
|-----------------------------|---|--|
| Uses advised against        | Not Applicable                                  |  |
| .Details of the supplier of | the safety data sheet                           |  |
| ······                      |   |  |
| Registered company name     | Leica Biosystems Amsterdam                      |  |
| Address                     | Vlierweg 20 Amsterdam noord holland Netherlands |  |
| Telephone                   | +31-206919181                                   |  |
| Fax                         | +31-206963531                                   |  |
| Website                     | wanted aligned and a second                     |  |

| Website | www.LeicaBiosystems.com              |
|---------|--------------------------------------|
| Email   | kreatech-support@leicabiosystems.com |

## 1.4.Emergency telephone number

| Association / Organisation        | Leica Biosystems |
|-----------------------------------|------------------|
| Emergency telephone<br>numbers    | +31-206919181    |
| Other emergency telephone numbers | Not Available    |

# SECTION 2 HAZARDS IDENTIFICATION

## 2.1.Classification of the substance or mixture

| Classification according to<br>regulation (EC) No<br>1272/2008 [CLP] <sup>[1]</sup> | Reproductive Toxicity Category 1B   |  |
|---|---|--|
| 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 |  |
| 2.2. Label elements   |   |  |
| CLP label elements  |   |  |
| SIGNAL WORD   | DANGER  |  |
| Hazard statement(s)   |   |  |
| H360D   | May damage the unborn child   |  |

Continued...

# Kreatech FISH probe ROW

| P201                          | Obtain special instructions before use.                                    |
|-------------------------------|--|
| P280                          | Wear protective gloves/protective clothing/eye protection/face protection. |
|                               |  |
| Precautionary statement(s) F  | Response   |
| D200 - D242                   | IF exposed or concerned: Get medical advice/attention.                     |
| P308+P313                     | r exposed of concerned. Get medical advice/attention.                      |
| P308+P313                     | ir exposed of concerned. Get medical advice/attention.                     |
| Precautionary statement(s) \$ |  |
|                               |  |
| Precautionary statement(s) S  | Storage  |
| Precautionary statement(s) S  | Storage<br>Store locked up.  |

#### 2.3. Other hazards

formamide L

Listed in the European Chemicals Agency (ECHA) Candidate List of Substances of Very High Concern for Authorisation

## SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

# 3.1.Substances

See 'Composition on ingredients' in Section 3.2

## 3.2.Mixtures

| 1.CAS No<br>2.EC No<br>3.Index No   | %[weight] | Name   | Classification according to regulation (EC) No 1272/2008 [CLP]   |
|---|-----------|--|--|
| 4.REACH No  | 1         |  |  |
| 1.7732-18-5*<br>2.231-791-2<br>3.Not Available<br>4.Not Available   | 20-50     | water  | Not Applicable   |
| 1.75-12-7<br>2.200-842-0<br>3.616-052-00-8<br>4.01-2119496064-35-XXXX,<br>01-2119841903-36-XXXX,<br>01-2119856136-36-XXXX | 20-50     | formamide  | Repr. 1B; H360D *** <sup>[3]</sup>   |
| 1.9063-02-9<br>2.Not Available<br>3.Not Available<br>4.Not Available  | 5-20      | dextran sulfate  | Not Applicable   |
| 1.7647-14-5<br>2.231-598-3<br>3.Not Available<br>4.01-2119485491-33-XXXX  | <1        | sodium chloride  | Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, STOT - SE (Resp. Irr.) Category 3; H315, H319, H335 <sup>11</sup> |
| 1.6132-04-3<br>2.200-675-3<br>3.Not Available<br>4.01-2119457027-40-XXXX  | <1        | sodium citrate<br>dihydrate                            | Not Applicable   |
| Legend:   |           | by Chemwatch; 2. Classi<br>. Classification drawn fror | fication drawn from EC Directive 67/548/EEC - Annex I; 3. Classification drawn from EC Directive 1272/2008<br>n 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> <li>Immediately give a glass of water.</li> <li>First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> <li>If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>Other measures are usually unnecessary. If</li> <li>this product comes in contact with eyes:</li> <li>Wash out immediately with water.</li> <li>If irritation continues, seek medical attention.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled</li> <li>personnel. If skin or hair contact occurs:</li> <li>Flush skin and hair with running water (and soap if</li> <li>available). Seek medical attention in event of irritation.</li> </ul> |
|-------------|--|
| Eye Contact | <ul> <li>If this product comes in contact with eyes:</li> <li>Wash out immediately with water.</li> <li>If irritation continues, seek medical attention.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>   |

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

## 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**

# 5.1. Extinguishing media

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

• Water spray or fog - Large fires only.

## 5.2. 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  |
|------------------------------|---|
| 5.3. Advice for firefighters |   |
| Fire Fighting                | <ul> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear full body protective clothing with breathing apparatus.</li> <li>Prevent, by any means available, spillage from entering drains or water course.</li> <li>Use water delivered as a fine spray to control fire and cool adjacent area.</li> <li>Avoid spraying water onto liquid pools.</li> <li>DO NOT approach containers suspected to be hot.</li> <li>Cool fire exposed containers with water spray from a protected location.</li> <li>If safe to do so, remove containers from path of fire.</li> </ul> |
| Fire/Explosion Hazard        | <ul> <li>Combustible.</li> <li>Slight fire hazard when exposed to heat or flame.</li> <li>Heating may cause expansion or decomposition leading to violent rupture of containers.</li> <li>On combustion, may emit toxic fumes of carbon monoxide (CO).</li> <li>May emit acrid smoke.</li> <li>Mists containing combustible materials may be explosive.</li> <li>Combustion products include:, carbon dioxide (CO2), nitrogen oxides (NOx), other pyrolysis products typical of burning organic materialMay emit poisonous fumes.</li> </ul>  |

## SECTION 6 ACCIDENTAL RELEASE MEASURES

|                                 | See section 8  |
|---------------------------------|--|
| 6.2. Environmental precaution   | ns   |
|                                 | See section 12   |
| 6.3. Methods and material fo    | r containment and cleaning up  |
| Minor Spills                    | <ul> <li>Remove all ignition sources.</li> <li>Clean up all spills immediately.</li> <li>Avoid breathing vapours and contact with skin and eyes.</li> <li>Control personal contact with the substance, by using protective</li> <li>equipment. Contain and absorb spill with sand, earth, inert material</li> <li>or vermiculite. Wipe up.</li> <li>Place in a suitable, labelled container for waste disposal.</li> </ul> |
| Major Spills                    |  |
| 6.4. Reference to other section | ons  |
|                                 | Personal Protective Equipment advice is contained in Section 8 of the SDS.   |
|                                 |  |
| SECTION 7 HANDLING A            | ND STORAGE   |

# • Wear protective clothing when risk of exposure occurs.

| Safe handling | Use in a well-ventilated area.                                    |
|---------------|---|
| j             | Prevent concentration in hollows and sumps.                       |
|               | • DO NOT enter confined spaces until atmosphere has been checked. |

Avoid all personal contact, including inhalation.

|                                  | <ul> <li>DO NOT allow material to contact humans, exposed food or food</li> <li>utensils. Avoid contact with incompatible materials.</li> <li>When handling, DO NOT eat, drink or smoke.</li> <li>Keep containers securely sealed when not in</li> <li>use. Avoid physical damage to containers.</li> <li>Always wash hands with soap and water after handling.</li> <li>Work clothes should be laundered separately. Launder contaminated clothing</li> <li>before re-use. Use good occupational work practice.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul> |
|----------------------------------|--|
| Fire and explosion<br>protection | See section 5  |
| Other information                | <ul> <li>Store in original containers.</li> <li>Keep containers securely sealed.</li> <li>No smoking, naked lights or ignition sources.</li> <li>Store in a cool, dry, well-ventilated area.</li> <li>Store away from incompatible materials and foodstuff containers.</li> <li>Protect containers against physical damage and check regularly for leaks.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>   |

## 7.2. Conditions for safe storage, including any incompatibilities

| Suitable container      | <ul> <li>DO NOT use mild steel or galvanised containers</li> <li>Metal can or drum</li> <li>Packaging as recommended by manufacturer.</li> <li>Check all containers are clearly labelled and free from leaks.</li> </ul>  |
|-------------------------|---|
| Storage incompatibility | <ul> <li>Formamide: <ul> <li>may be light- and impact-sensitive</li> <li>reacts slowly with water forming hydrocyanic acid and ammonium formate - this reaction will be sped up by elevated temperatures or increase or decrease in pH</li> <li>reacts violently, possibly explosively, when mixed with furfuryl alcohol, hydrogen peroxide, nitromethane, phosphorus pentoxide, titanium nitrate</li> <li>is incompatible with strong oxidisers, acids, bases, alkali metal acetates, ammonia, cellulose acetate, cresols, iodine, isocyanates, lignin, metal chlorides, nitrates, oleum, phenols, polyvinyl alcohol, pyridines, starch, inorganic sulfates, sulfur trioxide, tannins</li> <li>attacks metals, including brass and copper, and their alloys, aluminium, cobalt, iron, lead, nickel, tin, zinc</li> <li>attacks some plastics, coatings, rubbers and glues</li> <li>thermal decomposition may produce ammonia, oxides of carbon and nitrogen, and hydrogen cyanide</li> <li>Avoid reaction with oxidising agents</li> </ul></li></ul> |

## 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         |
|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| Not Available |

| EMERGENCY LIMITS         |   |               |           |            |
|--------------------------|---|---------------|-----------|------------|
| Ingredient               | Material name                           | TEEL-1        | TEEL-2    | TEEL-3     |
| formamide                | Formamide                               | 13 ppm        | 13 ppm    | 600 ppm    |
| sodium chloride          | Chloride; (Chloride(1-); Chloride ions) | 1 ppm         | 2.52 ppm  | 30 ppm     |
| sodium chloride          | Sodium chloride                         | 11 mg/m3      | 120 mg/m3 | 1100 mg/m3 |
| sodium citrate dihydrate | Citric acid, trisodium salt, dihydrate  | 9.3 mg/m3     | 100 mg/m3 | 610 mg/m3  |
| sodium citrate dihydrate | Trisodium citrate                       | 9.3 mg/m3     | 100 mg/m3 | 610 mg/m3  |
|                          |   |               |           |            |
| Ingredient               | Original IDLH                           | Revised IDLH  |           |            |
| water                    | Not Available                           | Not Available |           |            |
| formamide                | Not Available                           | Not Available |           |            |
| dextran sulfate          | Not Available                           | Not Available |           |            |
| sodium chloride          | Not Available                           | Not Available |           |            |
| sodium citrate dihydrate | Not Available                           | Not Available |           |            |

#### 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<br>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<br>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<br>f/min)    |
| 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<br>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> <li>Safety glasses with side</li> <li>shields Chemical goggles.</li> <li>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]</li> </ul> |
| Skin protection            | See Hand protection below  |
| Hands/feet protection      | Not Applicable   |
| Body protection            | See Other protection below   |
| Other protection           | Not Applicable   |
| Thermal hazards            | Not Available  |

#### **Respiratory protection**

Type A 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        | Not Available |
|                  |               | n-octanol / water            | The standard  |
| Odour threshold  | Not Available | Auto-ignition temperature    | Not Available |
|                  |               | (°C)                         | Not Available |
| pH (as supplied) | Not Available | Decomposition                | Not Available |
|                  |               | temperature                  |               |

| Melting point / freezing<br>point (°C)          | Not Available | Viscosity (cSt)                     | Not Available |
|---|---------------|-------------------------------------|---------------|
| Initial boiling point and<br>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<br>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

# SECTION 10 STABILITY AND REACTIVITY

| 10.1.Reactivity                             | See section 7.2  |
|---|--|
| 10.2.Chemical stability                     | <ul> <li>Unstable in the presence of incompatible</li> <li>materials. Product is considered stable.</li> <li>Hazardous polymerisation will not occur.</li> </ul> |
| 10.3. Possibility of<br>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. Effects and symptoms caused by hydrogen cyanide depends on the intensity and duration of exposure. Short term inhalation of 20-40 ppm hydrogen cyanide may result in slight symptoms, while 270 ppm can be fatal in one minute.  |
|--------------|--|
| Ingestion    | Rats fed formamide for up to ten days, at 1.5 g/kg, all died. Autopsy indicated a cumulative effect with changes characteristic of gastritis and malnutrition<br>The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of<br>corroborating animal or human evidence.   |
| 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.<br>The material is unlikely to produce an irritant dermatitis as described in EC Directives .<br>Open cuts, abraded or irritated skin should not be exposed to this material<br>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin<br>prior to the use of the material and ensure that any external damage is suitably protected.   |
| 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      | Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.<br>Repeated exposure to formamide may affect the central nervous system and may cause liver and kidney damage. Rats treated with 3000 mg/kg formamide by semiocclusive patches to the skin, 6 hours/day, 5 days/week for 3 months showed general poor health including a number of organ weight changes. Rats receiving 300 mg/kg developed polycythaemia.<br>Formamide is listed as a 'suggested' teratogen. This possible hazard should be discussed with all employees who may become pregnant.<br>Although it has been reported that application of formamide to the skin of pregnant mice resulted in the inhibition of foetal growth and foetal malformations, gross foetal abnormalities were not observed following dermal application to rats. In mice such effects were weak and could only be produced by application of large volumes. |

| Kreatech FISH probe ROW | TOXICITY<br>Not Available   | IRRITATION<br>Not Available       |
|-------------------------|---|-----------------------------------|
| water                   | TOXICITY<br>Not Available   | IRRITATION<br>Not Available       |
| formamide               | TOXICITY           dermal (rat) LD50: >3000 mg/kg <sup>[1]</sup> Inhalation (rat) LC50: >21 mg/l4 h <sup>[1]</sup> Inhalation (rat) LC50: >3900 ppm/6H <sup>[2]</sup> Oral (rat) LD50: ca.3200 mg/kg <sup>[1]</sup> | IRRITATION<br>Eye (rabbit): 23 mg |

|                         | extracted from RTECS - Register of Toxic Effect of chemical Substances  |
|-------------------------|---|
| Kreatech FISH probe ROW | No algorithment acute sociological data identified in literature<br>scure society. For formamidae:<br>Acute society. Toxicxivents turbles with rats or mice following a single onl administration showed that formamide was rapidly and<br>completely absorbed in rats and mole, with peak plasma levels occurring within 2.1. The elimination half-levels about 3.5 in the acute 3.1<br>in mice. The metabolism and distance of the society and mole studied in rats and mole trade with 1.6-1.6ebiled formamide vas a curring within 2.1. The elimination acute 3.1<br>in mice. The metabolism and distance of the society and mole studies of mole and mole trade with 1.6-1.6ebiled formamide vas a curring within 2.1. The elimination of the society is a society of the |
| FORMAMIDE               | for formamide:<br>Acute toxicity: Toxicokinetic studies with rats or mice following a single oral administration showed that formamide was rapidly and<br>completely absorbed in rats and mice, with peak plasma levels occurring within 2 h. The elimination half-life was about 15 h in rats and 4-6 h<br>in mice. The metabolism and distribution of formamide were studied in rats and mice treated with 14C-labelled formamide via intravenous<br>injection or inhalation exposure. The results showed that about 30% of formamide was excreted unchanged in urine within 72 h; about 30%<br>(for rats) or 50% (for mice) was excreted as carbon dioxide in breath, and only a minor quantity (1-3%) was excreted in the faeces. It was<br>suggested that cytochrome P450 2E1 was the primary enzyme of formamide metabolism<br><b>Repeat dose toxicity</b> : In repeated-dose short-term and subchronic toxicity studies, the main effects found in rats or mice include changes in<br>haematological parameters, irrespective of route of exposure. In a subchronic study, an oral LOAEL of 40 mg/kg-bw per day was determined based on<br>significant increases in haematocrit values, haemoglobin concentrations and erythrocyte counts in both male and female F344/N rats administered 0, 10,<br>20, 40, 80 or 160 mg formamide/kg-bw ger day by agave 5 days/week for 14 weeks. The incidences of degeneration of the germinal entihelium of the  |

Significant increases in hadmatocht values, naemoglobin concentrations and erythocyte counts in both male and refrate F344/N rats administered 0, 10, 20, 40, 80 or 160 mg formamide/kg-bw per day by gavage, 5 days/week for 14 weeks. The incidences of degeneration of the germinal epithelium of the testes and epididymis were significantly increased in males at the highest dose. The same oral LOAEL of 40 mg/kg-bw per day was also obtained based on a significant decrease in body weight gains in male B6C3F1 mice administered 0, 10, 20, 40, 80 or 160 mg formamide/kg-bw per day by gavage, 5 days/week for 14 weeks. Increased incidences of non-neoplastic lesions (hyperplasia and inflammation) were seen in pancreatic ducts at the dose of 80 mg/kg-bw per day. In a short-term study, a higher oral LOAEL of 113 mg/kg-bw per day was identified based on changes in haematological parameters,

| increases in micronucleated erythrocytes in male or female mice treated with formamide (0-160 mg/kg-bw per day) by gavage for 3 months,<br>although in another study, a dose-dependent increase in the number of polychromatic erythrocytes containing micronuclei was seen in bone<br>marrow of mice exposed to formamide via intraperitoneal injection at higher doses (225-1800 mg/kg-bw), with significance at doses of 900<br>mg/kg-bw or higher. However, at the dose of 160 mg/kg-bw, increased incidences of lesions of several tissues/organs and decreased body<br>weights were seen in mice, suggesting that the observed induction of micronuclei may be attributed to the cell damage.<br>In a review paper on the biological effects of formamide, it was suggested that formamide caused cancer by a non-genotoxic mode of action . Based of<br>the evidence of carcinogenicity observed in only one organ (liver), one sex (male) and one species (mice) and the conclusion that formamide is n<br>mutagenic, the tumours observed in the experimental animals are unlikely to have resulted from direct interaction with genetic material.<br>The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants<br>may produce conjunctivitis.<br>Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). | on  |  |
|---|---|--|
| <ul> <li>SODIUM CHLORIDE</li> <li>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</li> </ul>   | known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for<br>the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like<br>symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to<br>severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also<br>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<br>concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of<br>exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder<br>is characterised by dyspnea, cough and mucus production.<br>The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritatins may produce conjunctivitis.<br>The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the |  |
| SODIUM CITRATE         mg/kg/d. The major, reversible (sub)chronic toxic effects seem to be limited to changes in blood chemistry and metal absorption/excretion kinetics. Citric acid is no suspected of being a carcinogen nor a reprotoxic or teratogenic agent. The NOAEL for reproductive toxicity for rats is 2500 mg/kg/d.   | Based on many experimental data in animals and on human experience, citric acid is of low acute toxicity. The NOAEL for repeated dose toxicity for rats is 1200 mg/kg/d. The major, reversible (sub)chronic toxic effects seem to be limited to changes in blood chemistry and metal absorption/excretion kinetics. Citric acid is not suspected of being a carcinogen nor a reprotoxic or teratogenic agent. The NOAEL for reproductive toxicity for rats is 2500 mg/kg/d. Further, it is not mutagenic <i>in vitro</i> and <i>in vivo</i> . Also, the sensitising potential is seen as low. In contrast, irritation, in particular of the eyes  |  |
| water & DEXTRAN<br>SULFATE  |   |  |
| Acute Toxicity 🛇 Carcinogenicity 🛇  |   |  |
| Skin Irritation/Corrosion     Image: Skin Irritation/Corrosion     Image: Skin Irritation/Corrosion   |   |  |
| Serious Eye<br>Damage/Irritation     STOT - Single Exposure   |   |  |
| Respiratory or Skin<br>sensitisation STOT - Repeated Exposure   |   |  |

Mutagenicity

Aspiration Hazard

Legend: V -

8

👽 – Data required to make classification available

- Data available but does not fill the criteria for classification
  - Data Not Available to make classification

#### **SECTION 12 ECOLOGICAL INFORMATION**

#### 12.1. Toxicity

Environmental fate: Formamide may be released into the environment as a result of its production and use as solvent in manufacturing and processing plastics, non-aqueous electrolysis, and crystallization of pharmaceuticals and separation of chlorosilanes. According to Level III fugacity modeling, formamide will partition primarily in water and soil, depending on the compartment of release. Study shows that formamide is readily biodegradable in water, soil and sediment. Therefore, the compound is not expected to persist in soil and sediment. If released to air, formamide is expected to exist solely as a vapor in the ambient atmosphere based on the model of gas/particle partitioning of semivolatile organic compounds in the atmosphere. Vapor-phase formamide will be degraded in the atmosphere by reaction with photochemically produced hydroxyl radicals. Ecotoxicity: Experimental data shows that formamide does not cause significant effect to aquatic organisms at low concentration. Likewise, modelled toxicity data shows that formamide does not expected to cause ecological harm at environmental concentrations.

Fish LC50 (96h): golden orfe (Leuciscus idus) 6.57 mg/l; zebra fish (Danio rerio) 9.14 mg/l Amphipod EC50 (96h): Chaetogammarus marinus 19 mg/l Daphnia magna EC50 (48h): >500 mg/l Algae EC50 (72h): Scenedesmus subspicatus >500 mg/l Lemna minor EC50 (24h): 81.2 mg/l Modelled data: Fish LC50 (96h): 82.6 mg/l (ECOSAR) Daphnia LC50 (48h): 69 mg/l (ECOSAR)

Shrimp LC50 (96h): 313 mg/l (ECOSAR) Alga EC50 (96h): 35 mg/l (ECOSAR)

#### For the Alkali Metal Cyanides:

Atmospheric Fate: It is unknown if atmospheric photolysis is an important fate process for alkali metal cyanides. Hydrogen cyanide is very resistant to photolysis in normal sunlight. The most important reaction of hydrogen cyanide in air is the reaction with photochemically-generated hydroxyl radicals and subsequent rapid oxidation to carbon monoxide (CO) and nitric oxide (NO); photolysis and reaction with ozone are not important transformation processes and reaction with singlet oxygen is not a significant transformation process except at stratospheric altitudes. The residence time for the reaction of hydrogen cyanide vapor with hydroxyl radicals in the atmosphere is approximately 2 years.

Terrestrial Fate: Low concentrations of cyanide in soil biodegrade under aerobic conditions. Under anaerobic conditions, cyanides ions will denitrify to gaseous nitrogen. Complexation reactions with metal ions may occur in soil and cyanide ions are sorbed by various natural media, including clays, biological solids and sediments. Hydrogen cyanide and the alkali metal cyanides are not likely to be strongly sorbed onto sediments and suspended solids. Cyanides are fairly mobile in soil. Mobility is lowest in low pH soils with high concentrations of free iron oxides, positively charged particles and clays and highest in soils with high pH, high concentrations of free calcium carbonate (CaCO3), negatively charged particles and low clay content. In soils where cyanide levels are high enough to be toxic to microorganisms, this compound may leach into groundwater. Volatilization of hydrogen cyanide would be a significant loss mechanism from soil surfaces at a pH <9.2. Aquatic Fate: The alkali metal cyanides are very soluble in water and readily dissociate. Depending on the pH of the water, the resulting cyanide ion may form hydrogen cyanide or react with various metals. The proportion of hydrogen cyanide formed from soluble cyanides increases as the water pH decreases. Volatilization is the dominant mechanism for the removal of free cyanide from water and is most effective under conditions of high temperatures, high dissolved oxygen levels, and at increased concentrations of atmospheric carbon dioxide. Insoluble metal cyanides are not expected to degrade to hydrogen cyanide. Oxidation, hydrolysis, and photolysis are the three predominant chemical processes that may cause loss of simple cyanides in aquatic media. Certain cyanides are oxidized to isocyanates by strong oxidizing agents which may be further hydrolyzed to ammonia and carbon dioxide; however, it has not yet been determined whether this is a significant fate process in waters containing peroxy radicals. Hydrogen cyanide can be hydrolyzed to formamide, which is subsequently hydrolyzed to ammonium and formate ions Volatilization is a significant and probably dominant fate process for hydrogen cyanide and the most common alkali metal cyanides (e.g., sodium and potassium cyanide) in surface water. Copper (I) cyanide is removed from water predominantly by sedimentation and biodegradation. Volatilization is not an important fate process for cyanide in groundwater and is expected to persist for considerably longer periods of time in underground aquifers than in surface water. Photocatalytic oxidation may not be significant in natural waters. In clear water, or at water surfaces, some metallocyanides may decompose to the cyanide ion by photodissociation and subsequently form hydrogen cyanide. Biodegradation is an important transformation process for cyanide in natural surface waters, and is dependent on such factors as cyanide concentration, pH, temperature, nutrient availability and microbial acclimation.

Ecotoxicity: Cyanide is toxic to microorganisms in low concentration; however, acclimation increases tolerance. Actinomyces, Alcaligenes, Arthrobacter, Bacillus, Micrococcus, Neisseria, Paracoccus, Pseudomonas, and Thiobacillus bacteria are particularly effective at cyanide degradation. Certain metal cyanide complexes may bioaccumulate in aquatic organisms. It is difficult to evaluate the toxicologic significance of bioaccumulation of metal cyanide complexes because these compounds are much less toxic than soluble hydrogen cyanide, sodium cyanide, or potassium cyanide. There is no evidence of bioagnification of cyanides in the food chain and accumulation of cyanide in food webs is not expected. **DO NOT** discharge into sewer or waterways.

## 12.2. Persistence and degradability

| Ingredient      | Persistence: Water/Soil | Persistence: Air |
|-----------------|-------------------------|------------------|
| water           | LOW                     | LOW              |
| formamide       | LOW                     | LOW              |
| sodium chloride | LOW                     | LOW              |

#### 12.3. Bioaccumulative potential

| Ingredient      | Bioaccumulation       |
|-----------------|-----------------------|
| water           | LOW (LogKOW = -1.38)  |
| formamide       | LOW (LogKOW = -1.51)  |
| sodium chloride | LOW (LogKOW = 0.5392) |

#### 12.4. Mobility in soil

| Ingredient      | Mobility           |
|-----------------|--------------------|
| water           | LOW (KOC = 14.3)   |
| formamide       | HIGH (KOC = 1.498) |
| sodium chloride | LOW (KOC = 14.3)   |

#### 12.5.Results of PBT and vPvB assessment

|                         | P             | В             | т             |
|-------------------------|---------------|---------------|---------------|
| Relevant available data | Not Available | Not Available | Not Available |
| PBT Criteria fulfilled? | Not Available | Not Available | Not Available |

Continued...

## 12.6. Other adverse effects

No data available

# SECTION 13 DISPOSAL CONSIDERATIONS

| 13.1. Waste treatment metho     | ds   |
|---------------------------------|--|
| Product / Packaging<br>disposal | <ul> <li>Containers may still present a chemical hazard/ danger when empty.</li> <li>Return to supplier for reuse/ recycling if possible. Otherwise:</li> <li>If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <li>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.</li> <li>A Hierarchy of Controls seems to be common - the user should investigate: <ul> <li>Reduction</li> <li>Reuse</li> <li>Recycling</li> <li>Disposal (if all else fails)</li> </ul> </li> <li>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.</li> <li>Do NOT allow wash water from cleaning or process equipment to enter drains.</li> <li>It may be necessary to collect all wash water for treatment before disposal.</li> <li>It may be necessary to collect all wash water for recycling options.</li> <li>Consult State Land Waste Authority for disposal.</li> <li>Bury or incinerate and an approved site.</li> <li>Bury or incinerate residue at an approved site.</li> </ul> |
| Waste treatment options         | Not Available  |
| Sewage disposal options         | Not Available  |

# SECTION 14 TRANSPORT INFORMATION

## Labels Required

Marine Pollutant NO

## 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<br>Subrisk Not Applicable  |  |
| 14.6. Special precautions for<br>user | Hazard identification (Kemler)<br>Classification code<br>Hazard Label<br>Special provisions<br>Explosive Limit and Limited Quantity Index<br>ERAP Index<br>Limited quantity | Not Applicable         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)   | ICAO/IATA Class     Not Applicable       ICAO / IATA Subrisk     Not Applicable       ERG Code     Not Applicable |  |
| 14.6. Special precautions for user | Special provisions<br>Cargo Only Packing Instructions<br>Cargo Only Maximum Qty / Pack                            | Not Applicable<br>Not Applicable<br>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  |
|   | Passenger and Cargo Maximum Qty / Pack<br>Passenger and Cargo Limited Quantity Packing Instructions |

#### 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)   | IMDG ClassNot ApplicableIMDG SubriskNot Applicable                                       |
| 14.6. Special precautions for user | EMS NumberNot ApplicableSpecial provisionsNot ApplicableLimited QuantitiesNot 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<br>class(es) | Not Applicable Not Applicable  |
| 14.6. Special precautions for user  | Classification codeNot ApplicableLimited quantityNot ApplicableEquipment requiredNot ApplicableFire cones numberNot Applicable |

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

| Source  | Ingredient | Pollution Category |
|---|------------|--------------------|
| IMO MARPOL 73/78 (Annex<br>II) - List of Noxious Liquid<br>Substances Carried in Bulk | formamide  | Y                  |

#### **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

EU REACH Regulation (EC) No 1907/2006 - Annex IV - Exemptions from the Obligation to Register in Accordance with Article 2(7)(a) (English) European Customs Inventory of Chemical Substances ECICS (English)

#### FORMAMIDE(75-12-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

EU REACH Regulation (EC) No 1907/2006 - Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles EU REACH Regulation (EC) No 1907/2006 - Annex XVII (Appendix 6) Toxic to reproduction: category 1B (Table 3.1)/category 2 (Table 3.2)

EU REACH Regulation (EC) No 1907/2006 - Proposals to identify Substances of Very High Concern: Annex XV reports for commenting by Interested Parties Europe AeroSpace and Defence Industries Association of Europe (ASD) REACH Implementation Working Group Priority Declarable Substances List (PDSL)

Europe European Chemicals Agency (ECHA) Candidate List of Substances of Very High Concern for Authorisation

European Customs Inventory of Chemical Substances ECICS (English)

DEXTRAN SULFATE(9063-02-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS Not Applicable

SODIUM CHLORIDE(7647-14-5) 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)

European Trade Union Confederation (ETUC) Priority List for REACH Authorisation European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

European Union (EU) Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances - updated by ATP: 31

European Union (EU) Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances (updated by ATP: 31) - Reprotoxic Substances

European Union (EU) Regulation (EC) No 1272/2008 on Classification,

Labelling and Packaging of Substances and Mixtures - Annex VI

Netherlands Non-exhaustive list of reproductive toxins which additional registration requirement applicable under Article 4.2a, second paragraph of the Working Conditions Decree (Dutch)

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

SODIUM CITRATE DIHYDRATE(6132-04-3) 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)

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, Commission Regulation (EU) 2015/830, 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                     | N (dextran sulfate)   |  |
| Canada - NDSL                    | N (water; sodium chloride; formamide; sodium citrate dihydrate)   |  |
| China - IECSC                    | Υ   |  |
| Europe - EINEC / ELINCS /<br>NLP | N (dextran sulfate)   |  |
| Japan - ENCS                     | N (water; dextran sulfate)  |  |
| Korea - KECI                     | Y   |  |
| New Zealand - NZIoC              | Υ   |  |
| Philippines - PICCS              | N (dextran sulfate)   |  |
| 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**

#### Full text Risk and Hazard codes

| H315      | Causes skin irritation           |
|-----------|----------------------------------|
| H319      | Causes serious eye irritation    |
| H335      | May cause respiratory irritation |
| H360D *** | H360D ***                        |

#### Other information

#### Ingredients with multiple cas numbers

| Name            | CAS No                            |
|-----------------|-----------------------------------|
| sodium chloride | 14762-51-7, 16887-00-6, 7647-14-5 |

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.

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