



Recombinant Human Transforming Growth Factor beta 3

Bright Biotech Limited

Part Number: **BB-0001**

Version No: **1.4**

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Initial Date: **10/12/2025**

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Print Date: **09/12/2025**

L.REACH.GBR.EN

SECTION 1 Identification of the substance / mixture and of the company / undertaking

1.1. Product Identifier

Product name	Recombinant Human Transforming Growth Factor beta 3
Synonyms	rh-TGFβ-3
Other means of identification	BB-0001

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

Relevant identified uses	Not Available
Uses advised against	No specific uses advised against are identified.

1.3. Details of the manufacturer or importer of the safety data sheet

Manufacturer/Supplier	Bright Biotech Limited
Address	40 Pencroft Way Manchester Greater Manchester M15 6SZ United Kingdom
Telephone	0161 503 0585
Fax	Not Available
Website	https://www.brightbiotech.co.uk
Email	info@brightbiotech.co.uk

1.4. Emergency telephone number

Association / Organisation	Not Available
Emergency telephone number(s)	Not Available
Other emergency telephone number(s)	Not Available

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments ^[1]	Non hazardous
Legend:	1. Classification by vendor; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2. Label elements

Hazard pictogram(s)	Not Applicable
Signal word	Not Applicable

Hazard statement(s)

Not Applicable

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

Material contains acetic acid glacial.

2.3. Other hazards

ethanol	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)
ethanol	The material within this SDS meets the criteria for persistent, bioaccumulative and toxic in accordance with Annex XIII.
acetic acid glacial	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)

This substance/mixture does not meet the criteria for classification as Persistent, Bioaccumulative, and Toxic (PBT) in accordance with Annex XIII, Commission Delegated Regulation (EU) 2017/2100, and Commission Regulation (EU) 2018/605.

This substance/mixture does not meet the criteria for classification as very Persistent and very Bioaccumulative (vPvB) in accordance with Annex XIII, Commission Delegated Regulation (EU) 2017/2100, and Commission Regulation (EU) 2018/605.

This substance/mixture does not meet the criteria for classification as Persistent, Mobile and Toxic (PMT) in accordance with Commission Delegated Regulation (EU) 2023/707.

This substance/mixture does not meet the criteria for classification as very Persistent and very Mobile (vPvM) in accordance with Commission Delegated Regulation (EU) 2023/707.

The substance/mixture does not contain components considered to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605, nor is it included in the list established under REACH Article 59(1), at concentrations equal to or greater than 0.1% (w/w).

No further product hazard information.

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 regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
1. 64-17-5 2.200-578-6 3.603-002-00-5 4.Not Available	20	ethanol	Flammable Liquids Category 2; H225 [2]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 64-19-7 2.200-580-7 3.607-002-00-6 4.Not Available	0.12	acetic acid glacial *	Flammable Liquids Category 3, Skin Corrosion/Irritation Category 1A; H226, H314 [2]	Skin Corr. 1A; H314: C ≥ 90 % Skin Corr. 1B; H314: 25 % ≤ C < 90 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %	Not Available

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1. CAS No 2. EC No 3. Index No 4. REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
				Acute M factor: Not Applicable Chronic M factor: Not Applicable	

Legend:

1. Classification by vendor; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

SECTION 4 First aid measures

4.1. Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
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

For acute or short term repeated exposures to ethanol:

- Acute ingestion in non-tolerant patients usually responds to supportive care with special attention to prevention of aspiration, replacement of fluid and correction of nutritional deficiencies (magnesium, thiamine pyridoxine, Vitamins C and K).
- Give 50% dextrose (50-100 ml) IV to obtunded patients following blood draw for glucose determination.
- Comatose patients should be treated with initial attention to airway, breathing, circulation and drugs of immediate importance (glucose, thiamine).
- Decontamination is probably unnecessary more than 1 hour after a single observed ingestion. Cathartics and charcoal may be given but are probably not effective in single ingestions.
- Fructose administration is contra-indicated due to side effects.

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	<ul style="list-style-type: none"> Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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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 full body protective clothing with breathing apparatus. Prevent, by any means available, spillage from entering drains or water course. Use water delivered as a fine spray to control fire and cool adjacent area. Avoid spraying water onto liquid pools. 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.
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Fire/Explosion Hazard	<p>WARNING: In use may form flammable/ explosive vapour-air mixtures.</p> <ul style="list-style-type: none">▶ Combustible.▶ Slight fire hazard when exposed to heat or flame.▶ Heating may cause expansion or decomposition leading to violent rupture of containers.▶ On combustion, may emit toxic fumes of carbon monoxide (CO).▶ May emit acrid smoke.▶ Mists containing combustible materials may be explosive. <p>Combustion products include: carbon dioxide (CO2) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.</p>
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SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none">▶ Remove all ignition sources.▶ 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	<ul style="list-style-type: none">▶ Clear area of personnel and move upwind.▶ Alert Fire Brigade and tell them location and nature of hazard.▶ Wear full body protective clothing with breathing apparatus.▶ Prevent, by all means available, spillage from entering drains or water courses.▶ Consider evacuation (or protect in place).▶ No smoking, naked lights or ignition sources.▶ Increase ventilation.▶ Stop leak if safe to do so.▶ Water spray or fog may be used to disperse / absorb vapour.▶ Contain or absorb spill with sand, earth or vermiculite.▶ Collect recoverable product into labelled containers for recycling.▶ Collect solid residues and seal in labelled drums for disposal.▶ Wash area and prevent runoff into drains.▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.▶ If contamination of drains or waterways occurs, advise emergency services.

6.4. Reference to other sections

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

SECTION 7 Handling and storage

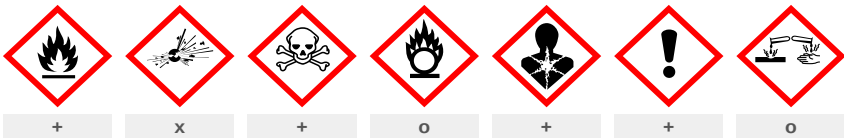
7.1. Precautions for safe handling

Safe handling	<ul style="list-style-type: none">▶ Avoid skin contact, including inhalation.▶ Wear protective clothing when risk of exposure occurs.▶ Use in a well-ventilated area.▶ Prevent concentration in hollows and sumps.▶ DO NOT enter confined spaces until atmosphere has been checked.▶ Avoid smoking, naked lights or ignition sources.▶ 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 SDS.▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions.▶ DO NOT allow clothing wet with material to stay in contact with skin
Fire and explosion protection	See section 5
Other information	<ul style="list-style-type: none">▶ Store in original containers.

- ▶ Keep containers securely sealed.
- ▶ No smoking, naked lights or ignition sources.
- ▶ Store in a cool, dry, well-ventilated area.
- ▶ Store away from incompatible materials and foodstuff containers.
- ▶ Protect containers against physical damage and check regularly for leaks.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none">▶ Metal can or drum▶ Packaging as recommended by manufacturer.▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Acetic acid: <ul style="list-style-type: none">▶ vapours forms explosive mixtures with air (above 39 C.)▶ reacts violently with bases such as carbonates and hydroxides (giving off large quantities of heat), oxidisers, organic amines, acetaldehyde, potassium tert-butoxide▶ reacts (sometimes violently), with strong acids, aliphatic amines, alkanolamines, alkylene oxides, epichlorohydrin, acetic anhydride, 2-aminoethanol, ammonia, ammonium nitrate, bromine pentafluoride, chlorosulfonic acid, chromic acid, chromium trioxide, ethylenediamine, ethyleneimine, hydrogen peroxide, isocyanates, oleum, perchloric acid, permanganates, phosphorus isocyanate, phosphorus trichloride, sodium peroxide, xylene▶ attacks cast iron, stainless steel and other metals, forming flammable hydrogen gas▶ attacks many forms of rubber, plastics and coatings▶ Avoid oxidising agents, acids, acid chlorides, acid anhydrides, chloroformates.▶ Avoid strong bases.
Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)	Not Available
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	Not Available



X — Must not be stored together
O — May be stored together with specific preventions
+ — May be stored together

Note: Depending on other risk factors, compatibility assessment based on the table above may not be relevant to storage situations, particularly where large volumes of dangerous goods are stored and handled. Reference should be made to the Safety Data Sheets for each substance or article and risks assessed accordingly.

7.3. Specific end use(s)
See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
ethanol	Dermal 343 mg/kg bw/day (Systemic, Chronic) Inhalation 380 mg/m³ (Systemic, Chronic) Inhalation 1900 mg/m³ (Local, Acute) Dermal 206 mg/kg bw/day (Systemic, Chronic) * Inhalation 114 mg/m³ (Systemic, Chronic) * Oral 87 mg/kg bw/day (Systemic, Chronic) * Inhalation 950 mg/m³ (Local, Acute) *	0.96 mg/L (Water (Fresh)) 2.75 mg/L (Water - Intermittent release) 0.79 mg/L (Water (Marine)) 3.6 mg/kg sediment dw (Sediment (Fresh Water)) 2.9 mg/kg sediment dw (Sediment (Marine)) 0.63 mg/kg soil dw (Soil) 580 mg/L (STP) 380 mg/kg food (Oral)
acetic acid glacial	Inhalation 25 mg/m³ (Local, Chronic) Inhalation 25 mg/m³ (Local, Acute) Inhalation 25 mg/m³ (Local, Chronic) * Inhalation 25 mg/m³ (Local, Acute) *	3.058 mg/L (Water (Fresh)) 30.58 mg/L (Water - Intermittent release) 0.306 mg/L (Water (Marine)) 11.36 mg/kg sediment dw (Sediment (Fresh Water)) 1.136 mg/kg sediment dw (Sediment (Marine)) 0.47 mg/kg soil dw (Soil) 85 mg/L (STP)

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs)	acetic acid glacial	Acetic acid	10 ppm / 25 mg/m3	50 mg/m3 / 20 ppm	Not Available	Not Available

MATERIAL DATA

For ethanol:
Odour Threshold Value: 49-716 ppm (detection), 101 ppm (recognition)
Eye and respiratory tract irritation do not appear to occur at exposure levels of less than 5000 ppm and the TLV-TWA is thought to provide an adequate margin of safety against such effects. Experiments in man show that inhalation of 1000 ppm caused slight symptoms of poisoning and 5000 ppm caused strong stupor and morbid sleepiness. Subjects exposed to 5000 ppm to 10000 ppm experienced smarting of the eyes and nose and coughing. Symptoms disappeared within minutes. Inhalation also causes local irritating effects to the eyes and upper respiratory tract, headaches, sensation of heat intraocular tension, stupor, fatigue and a need to sleep. At 15000 ppm there was continuous lachrymation and coughing.

These exposure guidelines have been derived from a screening level of risk assessment and should not be construed as unequivocally safe limits. ORGS represent an 8-hour time-weighted average unless specified otherwise.
CR = Cancer Risk/10000; UF = Uncertainty factor:
TLV believed to be adequate to protect reproductive health:
LOD: Limit of detection
Toxic endpoints have also been identified as:
D = Developmental; R = Reproductive; TC = Transplacental carcinogen
Jankovic J., Drake F.: A Screening Method for Occupational Reproductive
American Industrial Hygiene Association Journal 57: 641-649 (1996)

Exposed individuals are **NOT** reasonably expected to be warned, by smell, that the Exposure Standard is being exceeded.

Odour Safety Factor (OSF) is determined to fall into either Class C, D or E.

The Odour Safety Factor (OSF) is defined as:

OSF= Exposure Standard (TWA) ppm/ Odour Threshold Value (OTV) ppm

Classification into classes follows:
ClassOSF Description
A 550 Over 90% of exposed individuals are aware by smell that the Exposure Standard (TLV-TWA for example) is being reached, even when distracted by working activities
B 26-550 As "A" for 50-90% of persons being distracted
C 1-26 As "A" for less than 50% of persons being distracted
D 0.18-1 10-50% of persons aware of being tested perceive by smell that the Exposure Standard is being reached
E <0.18 As "D" for less than 10% of persons aware of being tested
for acetic acid:
NOTE:Detector tubes for acetic acid, measuring in excess of 1 ppm, are commercially available.
Exposure at or below the TLV-TWA and TLV-STEL is thought to protect the worker against conjunctival, nose and respiratory tract irritation.
Odour Safety Factor(OSF)
OSF=21 ("ACETIC ACID, GLACIAL")

8.2. Exposure controls

8.2.1. Appropriate engineering controls	<p>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.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>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.</p> <ul style="list-style-type: none">▶ Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.▶ Work should be undertaken in an isolated system such as a "glove-box" . Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.▶ Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.▶ Open-vessel systems are prohibited.▶ Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.▶ Exhaust air should not be discharged to regulated areas, non-regulated areas or the external environment unless decontaminated. Clean make-up air should be introduced in sufficient volume to maintain correct operation of the local
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	<p>exhaust system.</p> <ul style="list-style-type: none"> ▶ For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood. ▶ Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas). ▶ Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air. ▶ Laboratory hoods must be designed and maintained so as to draw air inward at an average linear face velocity of 0.76 m/sec with a minimum of 0.64 m/sec. Design and construction of the fume hood requires that insertion of any portion of the employees body, other than hands and arms, be disallowed.
8.2.2. Individual protection measures, such as personal protective equipment	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▶ 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].
Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber <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>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</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>As defined in ASTM F-739-96 in any application, gloves are rated as:</p> <ul style="list-style-type: none"> · Excellent when breakthrough time > 480 min · Good when breakthrough time > 20 min · Fair when breakthrough time < 20 min · Poor when glove material degrades <p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.</p> <p>It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of. · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential <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	<ul style="list-style-type: none"> ▶ Employees working with confirmed human carcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area. [AS/NZS ISO 6529:2006 or national equivalent] ▶ Employees engaged in handling operations involving carcinogens should be provided with, and required to wear and use half-face filter-type respirators with filters for dusts, mists and fumes, or air purifying canisters or cartridges. A respirator affording higher levels of protection may be substituted. [AS/NZS 1715 or national equivalent] ▶ Emergency deluge showers and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely.

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- ▶ Prior to each exit from an area containing confirmed human carcinogens, employees should be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers must be identified with suitable labels. For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood.
- ▶ Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
- ▶ Overalls.
- ▶ P.V.C apron.
- ▶ Barrier cream.
- ▶ Skin cleansing cream.
- ▶ Eye wash unit.

Ansell Glove Selection

Glove — In order of recommendation
AlphaTec® Solvex® 37-185
AlphaTec® 58-008
AlphaTec® Solvex® 37-675
AlphaTec® 79-700
MICROFLEX® 63-864
MICROFLEX® Diamond Grip® MF-300
AlphaTec® 38-612
TouchNTuff® 83-500
DermaShield™ 73-711
MICROFLEX® 93-260

The suggested gloves for use should be confirmed with the glove supplier.

Respiratory protection

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

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	AB-AUS	-	AB-PAPR-AUS / Class 1
up to 50 x ES	-	AB-AUS / Class 1	-
up to 100 x ES	-	AB-2	AB-PAPR-2 ^

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

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

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)	4.0	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available

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Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	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	Not Applicable	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	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 style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ 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 hazard classes as defined in Regulation (EC) No 1272/2008 Information on toxicological effects

a) Acute Toxicity	Based on available data, the classification criteria are not met.
b) Skin Irritation/Corrosion	Based on available data, the classification criteria are not met.
c) Serious Eye Damage/Irritation	Based on available data, the classification criteria are not met.
d) Respiratory or Skin sensitisation	Based on available data, the classification criteria are not met.
e) Mutagenicity	Based on available data, the classification criteria are not met.
f) Carcinogenicity	Based on available data, the classification criteria are not met.
g) Reproductivity	Based on available data, the classification criteria are not met.
h) STOT - Single Exposure	Based on available data, the classification criteria are not met.
i) STOT - Repeated Exposure	Based on available data, the classification criteria are not met.
j) Aspiration Hazard	Based on available data, the classification criteria are not met.

Inhaled	<p>Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system.</p> <p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.</p> <p>The most common signs of inhalation overexposure to ethanol, in animals, include ataxia, incoordination and drowsiness for those surviving narcosis. The narcotic dose for rats, after 2 hours of exposure, is 19260 ppm.</p>
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Continued...

Recombinant Human Transforming Growth Factor beta 3

	<p>The material has NOT been classified by EC Directives or other classification systems as "harmful by inhalation". This is because of the lack of corroborating animal or human evidence. In the absence of such evidence, care should be taken nevertheless to ensure exposure is kept to a minimum and that suitable control measures be used, in an occupational setting to control vapours, fumes and aerosols.</p>								
Ingestion	<p>Ingestion of ethanol (ethyl alcohol, "alcohol") may produce nausea, vomiting, bleeding from the digestive tract, abdominal pain, and diarrhoea. Effects on the body:</p> <table border="1"> <thead> <tr> <th>Blood concentration</th><th>Effects</th></tr> </thead> <tbody> <tr> <td><1.5 g/L</td><td>Mild: impaired vision, co-ordination and reaction time; emotional instability</td></tr> <tr> <td>1.5-3.0 g/L</td><td>Moderate: Slurred speech, confusion, inco-ordination, emotional instability, disturbances in perception and senses, possible blackouts, and impaired objective performance in standardized tests. Possible double vision, flushing, fast heart rate, sweating and incontinence. Slow breathing may occur rarely and fast breathing may develop in cases of metabolic acidosis, low blood sugar and low blood potassium. Central nervous system depression may progress to coma.</td></tr> <tr> <td>3-5 g/L</td><td>Severe: cold clammy skin, low body temperature and low blood pressure. Atrial fibrillation and heart block have been reported. Depression of breathing may occur, respiratory failure may follow serious poisoning, choking on vomit may result in lung inflammation and swelling. Convulsions due to severe low blood sugar may also occur. Acute liver inflammation may develop.</td></tr> </tbody> </table> <p>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.</p>	Blood concentration	Effects	<1.5 g/L	Mild: impaired vision, co-ordination and reaction time; emotional instability	1.5-3.0 g/L	Moderate: Slurred speech, confusion, inco-ordination, emotional instability, disturbances in perception and senses, possible blackouts, and impaired objective performance in standardized tests. Possible double vision, flushing, fast heart rate, sweating and incontinence. Slow breathing may occur rarely and fast breathing may develop in cases of metabolic acidosis, low blood sugar and low blood potassium. Central nervous system depression may progress to coma.	3-5 g/L	Severe: cold clammy skin, low body temperature and low blood pressure. Atrial fibrillation and heart block have been reported. Depression of breathing may occur, respiratory failure may follow serious poisoning, choking on vomit may result in lung inflammation and swelling. Convulsions due to severe low blood sugar may also occur. Acute liver inflammation may develop.
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<1.5 g/L	Mild: impaired vision, co-ordination and reaction time; emotional instability								
1.5-3.0 g/L	Moderate: Slurred speech, confusion, inco-ordination, emotional instability, disturbances in perception and senses, possible blackouts, and impaired objective performance in standardized tests. Possible double vision, flushing, fast heart rate, sweating and incontinence. Slow breathing may occur rarely and fast breathing may develop in cases of metabolic acidosis, low blood sugar and low blood potassium. Central nervous system depression may progress to coma.								
3-5 g/L	Severe: cold clammy skin, low body temperature and low blood pressure. Atrial fibrillation and heart block have been reported. Depression of breathing may occur, respiratory failure may follow serious poisoning, choking on vomit may result in lung inflammation and swelling. Convulsions due to severe low blood sugar may also occur. Acute liver inflammation may develop.								
Skin Contact	<p>Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.</p> <p>Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>								
Eye	<p>This material causes serious eye irritation.</p> <p>Direct contact of the eye with ethanol may cause immediate stinging and burning with reflex closure of the lid and tearing, transient injury of the corneal epithelium and hyperaemia of the conjunctiva. Foreign-body type discomfort may persist for up to 2 days but healing is usually spontaneous and complete.</p>								
Chronic	<p>Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems.</p> <p>Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.</p> <p>On the basis of epidemiological data, the material is regarded as carcinogenic to humans. There is sufficient data to establish a causal association between human exposure to the material and the development of cancer.</p> <p>Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.</p> <p>Serious damage (clear functional disturbance or morphological change which may have toxicological significance) is likely to be caused by repeated or prolonged exposure. As a rule the material produces, or contains a substance which produces severe lesions. Such damage may become apparent following direct application in subchronic (90 day) toxicity studies or following sub-acute (28 day) or chronic (two-year) toxicity tests.</p> <p>There is sufficient evidence to establish a causal relationship between human exposure to the material and impaired fertility</p> <p>Long-term exposure to ethanol may result in progressive liver damage with fibrosis or may exacerbate liver injury caused by other agents.</p> <p>Repeated ingestion of ethanol by pregnant women may adversely affect the central nervous system of the developing foetus, producing effects collectively described as foetal alcohol syndrome. These include mental and physical retardation, learning disturbances, motor and language deficiency, behavioural disorders and reduced head size.</p>								

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Consumption of ethanol (in alcoholic beverages) may be linked to the development of Type I hypersensitivities in a small number of individuals. Symptoms, which may appear immediately after consumption, include conjunctivitis, angioedema, dyspnoea, and urticarial rashes. The causative agent may be acetic acid, a metabolite (1).
(1) Boehncke W.H., & H.Gall, Clinical & Experimental Allergy, 26, 1089-1091, 1996

Recombinant Human Transforming Growth Factor beta 3	TOXICITY	IRRITATION
	Not Available	Not Available
ethanol	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 17100 mg/kg ^[1]	Eye (Rodent - rabbit): 0.1mL
	Inhalation (Rat) LC50: 64000 ppm4h ^[2]	Eye (Rodent - rabbit): 100mg/4S - Moderate
	Oral (Rat) LD50: 7060 mg/kg ^[2]	Eye (Rodent - rabbit): 100uL - Moderate
		Eye (Rodent - rabbit): 500mg - Severe
		Eye (Rodent - rabbit): 500mg/24H - Mild
		Eye (Rodent - rabbit): 50pph/1H - Mild
		Eye: adverse effect observed (irritating) ^[1]
		Eye: no adverse effect observed (not irritating) ^[1]
		Skin (Human): 70%/2D
		Skin (Rodent - rabbit): 20mg/24H - Moderate
		Skin (Rodent - rabbit): 400mg - Mild
		Skin: no adverse effect observed (not irritating) ^[1]
acetic acid glacial	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 1060 mg/kg ^[2]	Eye (Rodent - rabbit): 0.1mL
	Inhalation (Mouse) LC50: 1.405 mg/L4h ^[2]	Eye (Rodent - rabbit): 5mg/30S - Mild
	Oral (Rat) LD50: 3310 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Skin (Human): 50mg/24H - Mild
		Skin (Rodent - rabbit): 50mg/24H - Mild
		Skin (Rodent - rabbit): 525mg - Severe
		Skin: adverse effect observed (corrosive) ^[1]
		Skin: adverse effect observed (irritating) ^[1]
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

ETHANOL	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
ACETIC ACID GLACIAL	<p>for acid mists, aerosols, vapours</p> <p>Data from assays for genotoxic activity in vitro suggest that eukaryotic cells are susceptible to genetic damage when the pH falls to about 6.5. Cells from the respiratory tract have not been examined in this respect. Mucous secretion may protect the cells of the airways from direct exposure to inhaled acidic mists, just as mucous plays an important role in protecting the gastric epithelium from its auto-secreted hydrochloric acid. In considering whether pH itself induces genotoxic events in vivo in the respiratory system, comparison should be made with the human stomach, in which gastric juice may be at pH 1-2 under fasting or nocturnal conditions, and with the human urinary bladder, in which the pH of urine can range from <5 to="> 7 and normally averages 6.2. Furthermore, exposures to low pH in vivo differ from exposures <i>in vitro</i> in that, <i>in vivo</i>, only a portion of the cell surface is subjected to the adverse conditions, so that perturbation of intracellular homeostasis may be maintained more readily than in vitro.</p> <p>The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>The material may produce severe skin irritation after prolonged or repeated exposure, and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) thickening of the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. Prolonged contact is unlikely, given the severity of response, but repeated exposures may produce severe ulceration.</p> <p>NOAELs following repeated exposure to acetic acid and its salts range from 210 mg/kg bw/day (2-4 month acetic acid drinking water study; systemic toxicity) to 3600 mg/kg bw/day (acetic acid, sodium salt, 4 week dietary study; no effects reported). Signs of irritation/corrosion at the site of contact as well as systemic toxicity have been reported. Prolonged inhalation exposure to acetic acid results in muscle imbalance, increase in blood cholinesterase activity, decreases in albumins and decreased growth at concentrations greater than 0.01 mg/m3/day.</p> <p>Groups of 20 mice/sex were given 0.025% sodium acetate in drinking water (about 60 mg/kg bw/day) for 1 week before breeding, during a 9-day breeding period and (females only) throughout pregnancy, lactation and until the offspring were weaned at 3 weeks of age. No effects on fertility were observed. The male offspring were given the same solution until they were 5-7</p>

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	weeks old and were then examined in a 24-hour activity test. Examination of the litters revealed no overt deformities and normal pup weights at day 1 and day 21. The activity of offspring of the treated group was lower than that of controls during the first 12 hours but was similar during the second 12 hours. It is unknown if the decreased activity observed in the sodium acetate treated group to was a result of exposure in utero and/or post-weaning, since the pups were exposed during both time periods.). Acetic acid had no effects on implantation or on maternal or fetal survival in rats, mice or rabbits dosed via gavage during gestation days 6-19 at doses up to 1600 mg/kg/day. The number of abnormalities seen in either soft or skeletal tissues of the test groups did not differ from the number occurring in the controls. Sodium acetate had no effect on pregnant mice or offspring when mice were administered 1000 mg/kg bw, by gavage on days 8-12 of gestation.
Recombinant Human Transforming Growth Factor beta 3 & ACETIC ACID GLACIAL	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. 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. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

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 either not available or does not fill the criteria for classification
✓ – Data available to make classification

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

Recombinant Human Transforming Growth Factor beta 3	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
ethanol	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	275mg/l	2
	EC50	48h	Crustacea	2mg/L	4
	EC50	96h	Algae or other aquatic plants	<0.001mg/L	4
	EC50(ECx)	96h	Algae or other aquatic plants	<0.001mg/L	4
	LC50	96h	Fish	42mg/L	4
acetic acid glacial	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	29.23mg/l	2
	EC50	48h	Crustacea	18.9mg/l	2
	EC50	96h	Algae or other aquatic plants	73.4mg/L	4
	EC50(ECx)	24h	Algae or other aquatic plants	0.08mg/l	2
	LC50	96h	Fish	31.3-67.6mg/l	2

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. US EPA, Ecotox database - Aquatic Toxicity Data 4. ECETOC Aquatic Hazard Assessment Data 5. NITE (Japan) - Bioconcentration Data 6. METI (Japan) - Bioconcentration Data 7. Vendor Data

For Ethanol:

Continued...

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log Kow: -0.31 to -0.32;
 Koc 1: Estimated BCF= 3;
 Half-life (hr) air: 144;
 Half-life (hr) H2O surface water: 144;
 Henry's atm m3 /mol: 6.29E-06;
 BOD 5 if unstated: 0.93-1.67,63%
 COD: 1.99-2.11,97%;
 ThOD : 2.1.

Environmental Fate: Terrestrial - Ethanol quickly biodegrades in soil but may leach into ground water; most is lost by evaporation. Ethanol is expected to have very high mobility in soil. Volatilization of ethanol from moist soil surfaces is expected to be an important fate process. The potential for volatilization of ethanol from dry soil surfaces may exist. Biodegradation is expected to be an important fate process for ethanol based on half-lives on the order of a few days for ethanol in sandy soil/groundwater microcosms.

Atmospheric Fate: Ethanol is expected to exist solely as a vapour in the ambient atmosphere. Vapour-phase ethanol is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 5 days. Ethanol readily degraded by reaction with photochemically produced hydroxy radicals; release into air will result in photodegradation and wet deposition.

Aquatic Fate: When released into water ethanol readily evaporates and is biodegradable. Ethanol is not expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is expected and volatilization half-lives for a model river and model lake are 3 and 39 days, respectively. Bioconcentration in aquatic organisms is considered to be low. Hydrolysis and photolysis in sunlit surface waters is not expected to be an important environmental fate process for ethanol and is unlikely to be persistent in aquatic environments.

Acetic acid and its salts (the acetates) can be grouped together because of their close structural relationships, their natural occurrence in plants and animals, and their fundamental role in cell metabolism, particularly in the tricarboxylic acid cycle (also known as the citric acid or Krebs cycle), which is where humans get their energy.

- ▶ Acetic acid is degraded photochemically in the atmosphere to produce hydroxyl radicals (estimated typical half-life of 22 days). Physical removal of acetates on atmospheric particulates may occur via wet or dry deposition.
- ▶ Natural water will neutralise dilute solutions of acetic acid.
- ▶ Spills of acetic acid on soil will readily biodegrade - the biodegradation rate for acetic acid after 14 days under aerobic conditions is 74 days.
- ▶ In invertebrates the toxicity of acetic acid (EC50 = 50-450 mg/L, depending on test species) -under static conditions, the 48 hour EC50 value for acetic acid is 65 mg/L for aquatic invertebrates (the test media was not neutralised). When the test solutions are neutralised, to form acetates, the static 48 hour EC50 for acetic acid is 6000 mg/L. In renewal systems with aquatic invertebrates, 48 hour EC50s for acetic acid are 100 mg/L and 180 mg/L.
- ▶ Fish LC50 (96 h): 75-88 mg/L.
- ▶ Acetic acid is not expected to bioconcentrate in the aquatic system.
- ▶ Low concentrations of acetic acid are harmful to fish.
- ▶ Drinking water standards: none available.
- ▶ Soil Guidelines: none available.
- ▶ Air Quality Standards: none available

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)
acetic acid glacial	LOW	LOW

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
ethanol	LOW (LogKOW = -0.31)
acetic acid glacial	LOW (LogKOW = -0.17)

12.4. Mobility in soil

Ingredient	Mobility
ethanol	HIGH (Log KOC = 1)
acetic acid glacial	HIGH (Log KOC = 1)

12.5. Results of PBT and vPvB assessment

	P	B	T	PBT criteria fulfilled?	vP	vB	vPvB criteria fulfilled?
Recombinant Human Transforming Growth Factor beta 3	✗	✗	✗	No	✗	✗	No
ethanol	✓	✓	✓	Yes	✗	✗	No
acetic acid glacial	No data available	No data available	No data available	No	No data available	No data available	No

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

Continued...

No evidence of ozone depleting properties were found in the current literature.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none">▶ Containers may still present a chemical hazard/ danger when empty.▶ Return to supplier for reuse/ recycling if possible. Otherwise: <ul style="list-style-type: none">▶ 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.▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: <ul style="list-style-type: none">▶ Reduction▶ Reuse▶ Recycling▶ Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. 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. <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 or consult manufacturer for recycling options.▶ Consult State Land Waste Authority for disposal.▶ Bury or incinerate residue at an approved site.▶ Recycle containers if possible, or dispose of in an authorised landfill.	
	Waste treatment options	Not Available
	Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

14.1. UN number or ID number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	Class	Not Applicable
	Subsidiary Hazard	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Hazard identification (Kemler)	Not Applicable
	Classification code	Not Applicable
	Hazard Label	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Transport Category	Not Applicable
	Tunnel Restriction Code	Not Applicable

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

14.1. UN number	Not Applicable
14.2. UN proper shipping name	Not Applicable

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14.3. Transport hazard class(es)	ICAO/IATA Class	Not Applicable
	ICAO / IATA Subsidiary Hazard	Not Applicable
	ERG Code	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	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

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

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	IMDG Class	Not Applicable
	IMDG Subsidiary Hazard	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	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. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	Not Applicable	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Classification code	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Equipment required	Not Applicable
	Fire cones number	Not Applicable

14.7. Maritime transport in bulk according to IMO instruments

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

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
ethanol	Not Applicable
acetic acid glacial	Not Applicable

14.7.3. Transport in bulk in accordance with the IGC Code

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Product name	Ship Type
ethanol	Not Applicable
acetic acid glacial	Not Applicable

SECTION 15 Regulatory information

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

ethanol is found on the following regulatory lists

EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products - Annex II - List of Substances Prohibited in Cosmetic Products

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

Europe EC Inventory

Europe European Customs Inventory of Chemical Substances- ECICS

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

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

acetic acid glacial is found on the following regulatory lists

EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs)

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

Europe EC Inventory

Europe European Customs Inventory of Chemical Substances- ECICS

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

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

Additional Regulatory Information

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

Seveso Category	Not Available
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15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (ethanol; acetic acid glacial)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	All chemical substances in this product have been designated as TSCA Inventory 'Active'
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	Yes
UAE - Control List (Banned/Restricted Substances)	No (ethanol; acetic acid glacial)
Legend:	Yes = All CAS declared ingredients are on the inventory

Continued...

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National Inventory	Status
	No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	09/12/2025
Initial Date	10/12/2025

Full text Risk and Hazard codes

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.

Other information

Ingredients with multiple cas numbers

Name	CAS No
ethanol	64-17-5, 2348-46-1

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

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

Definitions and abbreviations

- ▶ PC—TWA: Permissible Concentration-Time Weighted Average
- ▶ PC—STEL: Permissible Concentration-Short Term Exposure Limit
- ▶ IARC: International Agency for Research on Cancer
- ▶ ACGIH: American Conference of Governmental Industrial Hygienists
- ▶ STEL: Short Term Exposure Limit
- ▶ TEEL: Temporary Emergency Exposure Limit,
- ▶ IDLH: Immediately Dangerous to Life or Health Concentrations
- ▶ ES: Exposure Standard
- ▶ OSF: Odour Safety Factor
- ▶ NOAEL: No Observed Adverse Effect Level
- ▶ LOAEL: Lowest Observed Adverse Effect Level
- ▶ TLV: Threshold Limit Value
- ▶ LOD: Limit Of Detection
- ▶ OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- ▶ BEI: Biological Exposure Index
- ▶ DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- ▶ MARPOL: International Convention for the Prevention of Pollution from Ships
- ▶ IMSBC: International Maritime Solid Bulk Cargoes Code
- ▶ IGC: International Gas Carrier Code
- ▶ IBC: International Bulk Chemical Code

- ▶ AIIC: Australian Inventory of Industrial Chemicals
- ▶ DSL: Domestic Substances List
- ▶ NDSL: Non-Domestic Substances List
- ▶ IECSC: Inventory of Existing Chemical Substance in China
- ▶ EINECS: European INventory of Existing Commercial chemical Substances
- ▶ ELINCS: European List of Notified Chemical Substances
- ▶ NLP: No-Longer Polymers
- ▶ ENCS: Existing and New Chemical Substances Inventory
- ▶ KECI: Korea Existing Chemicals Inventory
- ▶ NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- ▶ TSCA: Toxic Substances Control Act
- ▶ TCSI: Taiwan Chemical Substance Inventory
- ▶ INSQ: Inventario Nacional de Sustancias Químicas
- ▶ NCI: National Chemical Inventory

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▸ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances