SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture	PIRITEZE SYRUP
Registration number	-
Synonyms	PIRITEZE SYRUP 1 MG/ML (UK) * CETIRIZINE DIHYDROCHLORIDE, FORMULATED PRODUCT
Issue date	15-September-2014
Version number	04
Revision date	15-September-2014

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

Identified uses	Medicinal Product This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information None.

2.3. Other hazards This product is non-flammable.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
D-SORBITOL	38.0 - 39.0	50-70-4 200-061-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
GLYCERIN	17.0 - 18.0	56-81-5 200-289-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
Propylene glycol	4.0 - 5.0	57-55-6 200-338-0	-	-	
Classification:	**DSD:** -				
	CLP: -				
METHYL PARABEN	<1.0	99-76-3 202-785-7	-	-	
Classification:	**DSD:** R52/53				
	CLP: Skin Irrit. 2;H315				
SODIUM ACETATE ANHYDROUS	<1.0	127-09-3 204-823-8	-	-	
Classification:	**DSD:** -				
	CLP: -				
ACETIC ACID	<0.1	64-19-7 200-580-7	-	607-002-00-6	# B
Classification:	**DSD:** R10, C;R35				
	CLP: Flam. Liq. 3;H226, Skin Corr. 1A;H314				
CETIRIZINE DIHYDROCHLORIDE	<0.1	83881-52-1 -	-	-	
Classification:	**DSD:** Xn;R22				
	CLP: Acute Tox. 4;H302				
PROPYL PARABEN	<0.1	94-13-3 202-307-7	-	-	
Classification:	**DSD:** -				
	CLP: -				

Other components below reportable levels 35.0 - 40.0

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. If breathing is difficult, trained personnel should give oxygen. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Take off contaminated clothing and wash before reuse. Immediately flush skin with plenty of water. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without medical advice.
4.2. Most important symptoms and effects, both acute and delayed	The following adverse effects have been noted with therapeutic use of this material: irritability; somnolence; abdominal pain; sore throat; nausea.
4.3. Indication of any immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards	This product is non-flammable.
5.1. Extinguishing media	
Suitable extinguishing media	Water. Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Use water spray to reduce vapours or divert vapour cloud drift. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	No special control measures required for the normal handling of this product. Avoid prolonged exposure.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value
CETIRIZINE DIHYDROCHLORIDE (CAS 83881-52-1)	OHC	2
D-SORBITOL (CAS 50-70-4)	OHC	1
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3
	OHC	1
SODIUM ACETATE ANHYDROUS (CAS 127-09-3)	OHC	1

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3	Total vapour and particulates.
		10 mg/m3	Particulate.
		150 ppm	Total vapour and particulates.

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
ACETIC ACID (CAS 64-19-7)	TWA	25 mg/m3
		10 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls

Hazard guidance and control recommendations Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Syrup.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Expected to be non-flammable based on components present.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Ingestion	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms	The following adverse effects have been noted with therapeutic use of this material: irritability; somnolence; abdominal pain; sore throat; nausea.

11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
ACETIC ACID (CAS 64-19-7)		
Acute		
Inhalation		
LCLo	Rat	39.6 mg/l 4-hour exposure
Oral		
LD50	Rat	3310 mg/kg
CETIRIZINE DIHYDROCHLORIDE (CAS 83881-52-1)		
Acute		
Oral		
LD50	Rat	365 mg/kg
D-SORBITOL (CAS 50-70-4)		
Acute		
Oral		
LD50	Rat	15.9 g/kg
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
METHYL PARABEN (CAS 99-76-3)		
Acute		
Oral		
LD50	Mouse	> 8 g/kg
PROPYL PARABEN (CAS 94-13-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Respiratory sensitisation Not available.

Skin sensitisation None known.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

CETIRIZINE DIHYDROCHLORIDE

Ames
Result: negative
Notes: FDA Approval Package
Chromosomal Aberration Assay In Vitro, human lymphocytes
Result: negative
Notes: FDA Approval Package
In vivo Micronucleus
Result: negative
Species: Mouse
Notes: FDA Approval Package
In vivo Micronucleus
Result: negative
Species: Rat
Mouse Lymphoma Cell (L5178Y) Mutation Assay
Result: negative
Notes: FDA Approval Package

Carcinogenicity Not classifiable as to carcinogenicity to humans.

CETIRIZINE DIHYDROCHLORIDE

16 mg/kg/day, Species-specific
Result: Increase in benign tumours
Species: Mouse
Organ: Liver
Notes: FDA Approval Package

Carcinogenicity

CETIRIZINE DIHYDROCHLORIDE

20 mg/kg/day
Result: negative
Species: Rat
Notes: FDA Approval Package

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

CETIRIZINE DIHYDROCHLORIDE

135 mg/kg/day Embryo-foetal development
Result: Maternal toxicity; adverse foetal effects
Species: Rabbit
Notes: FDA Approval Package
25 mg/kg/day Embryo-foetal development
Result: Maternal NOAEL, Foetal NOAEL
Species: Rat
Notes: FDA Approval Package
45 mg/kg/day Embryo-foetal development
Result: Maternal NOAEL, Foetal NOAEL
Species: Rabbit
Notes: FDA Approval Package
64 mg/kg/day Female Fertility / Early Embryonic Developmen t Result: negative
Species: Mouse
75 - 225 mg/kg/day Embryo-foetal development
Result: Maternal toxicity; adverse effects on offspring.
Species: Rat
Notes: FDA Approval Package
96 mg/kg/day Embryo-foetal development
Result: Maternal NOAEL, Foetal NOAEL
Species: Mouse
Notes: FDA Approval Package

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not likely, due to the form of the product.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test results
ACETIC ACID (CAS 64-19-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	47 mg/l, 24 hours Static test
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	79 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	251 mg/l, 96 hours Static test
Microtox	EC50	Microtox	11 mg/l, 15 minutes
METHYL PARABEN (CAS 99-76-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	11.2 mg/l, 48 hours
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	59.5 mg/l, 96 hours
Chronic			
Crustacea	NOEC	Water flea (Daphnia magna)	0.2 mg/l, 21 days OECD 211
Propylene glycol (CAS 57-55-6)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours

Components		Species	Test results
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
SODIUM ACETATE ANHYDROUS (CAS 127-09-3)			
Chronic			
Other	LC50	Pseudomonas putida	7200 mg/l, 18 hours
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	7170 mg/l, 24 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	5000 mg/l, 24 hours Static test
		Fathead minnow (Adult Pimephales promelas)	13330 mg/l, 120 hours Static test
Microtox	EC50	Microtox	22500 mg/l, 15 minutes

* Estimates for product may be based on additional component data not shown.

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

Propylene glycol	1.3 - 2.3 years Estimated

Half-life (Photolysis-atmospheric)

ACETIC ACID	22 Days Estimated
Propylene glycol	32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACETIC ACID	95 %, 5 days Zahn-Wellens, Activated sludge
Propylene glycol	62 %, 5 days BOD5, Activated sludge
	79 %, 20 Days BOD20, Activated sludge
SODIUM ACETATE ANHYDROUS	100 %, 5 days Modified Zahn-Wellens, Activated sludge
	97.4 % Coupled Unit test (OECD 303A), Activated sludge

Percent degradation (Aerobic biodegradation-ready)

ACETIC ACID	99 %, 30 days Closed Bottle test, Activated sludge
METHYL PARABEN	89 % , 28 days, OECD 301B

Percent degradation (Anaerobic biodegradation)

Propylene glycol	100 %, 9 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

ACETIC ACID	-0.24
D-SORBITOL	-2.2
GLYCERIN	-1.76
METHYL PARABEN	1.96
PROPYL PARABEN	3.04
Propylene glycol	-1.35

Bioconcentration factor (BCF)

D-SORBITOL	1 Estimated
Propylene glycol	< 1 Estimated
SODIUM ACETATE ANHYDROUS	< 10 Measured, Leuciscus idus, golden ide/orfe

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ACETIC ACID	0.81 - 2.36 Measured
D-SORBITOL	0.3 Estimated

Mobility in general

Volatility

Henry's law

ACETIC ACID	0 atm m3/mol Measured, 25 C
D-SORBITOL	0 atm m^3/mol Estimated
Propylene glycol	0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN	3.04

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

ACETIC ACID (CAS 64-19-7)

Directive 94/33/EC on the protection of young people at work

ACETIC ACID (CAS 64-19-7)

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R10 Flammable. R22 Harmful if swallowed. R35 Causes severe burns. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H226 Flammable liquid and vapour. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H315 Causes skin irritation.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Transport Information: Agency Name and Packaging Type/Transport Mode Selection GHS: Classification
Training information	Follow training instructions when handling this material.
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.