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	AMERGE TABLETS
Registration number	-
Synonyms	AMERGE TABLETS 1.0 MG * AMERGE TABLETS 2.5 MG * NARAGRAN TABLETS 2.5 MG * NARAMIG TABLETS 2.5 MG * NARATRIPTAN HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	15-July-2013
Version number	11
Revision date	15-July-2013

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 Not applicable.

2.3. Other hazards Caution - Pharmaceutical agent.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
NARATRIPTAN HYDROCHLORIDE	0.3 to 0.8	143388-64-1 -	-	-	
Classification:	**DSD:** Repr. Cat. 3;R62-63, Xn;R22				
	CLP: Acute Tox. 4;H302, Repr. 2;H361, STOT RE 2;H373				
Titanium dioxide	1.2 to 3.6	13463-67-7 236-675-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
Other components below reportable levels	>94.0				

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.

4.1. Description of first aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.

Eye contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Ingestion Rinse mouth thoroughly. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

4.2. Most important symptoms and effects, both acute and delayed The following adverse effects have been noted with therapeutic use of this material: tingling; nausea; vomiting; pain; increased blood pressure; dizziness; fatigue; incoordination.

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 local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder.

Unsuitable extinguishing media Carbon dioxide (CO2).

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 In the event of fire, cool tanks with water spray.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. For personal protection, see section 8.

For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Stop the flow of material, if this is without risk. Following product recovery, flush area with water.
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	Avoid breaking or crushing tablets. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash hands thoroughly after handling. Practice good housekeeping.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a well-ventilated place. Guard against dust accumulation of this material. Store away from incompatible materials (see Section 10 of the MSDS).
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	Note
NARATRIPTAN HYDROCHLORIDE (CAS 143388-64-1)	15 MIN STEL	50 mcg/m3	Reproductive hazard
	8 HR TWA	25 mcg/m3	
	OHC	3	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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. An eye wash station should be available.
Eye/face protection	Wear safety glasses with side shields (or goggles). (eg. EN 166) Wear a full-face respirator, if needed.
Skin protection	
- Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

Hygiene measures	When using, do not eat, drink or smoke. Wash hands after handling and before eating. An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

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	Solid.
Form	Tablet.
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	Not available.
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)	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. Fluorine.
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	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion	May be harmful if swallowed.

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: tingling; nausea; vomiting; pain; increased blood pressure; dizziness; fatigue; incoordination.

11.1. Information on toxicological effects

Components	Species	Test results
NARATRIPTAN HYDROCHLORIDE (CAS 143388-64-1)		
Acute		
Oral		
LD	Mouse	> 1000 mg/kg
	Rat	> 750 mg/kg
Subchronic		
Oral		
NOAEL	Rat	170 mg/kg/day, 6 months
NOEL	Dog	2.25 mg/kg/day, 12 months
	Rat	10 mg/kg/day, 6 months
TD	Rat	340 mg/kg/day, 6 months, Testes, Epididymides, Ovaries
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years, TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years, Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks, Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks, No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min, Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

* 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.

Corrosivity

NARATRIPTAN HYDROCHLORIDE — 50 %, formulated in soft paraffin.
Result: Non-irritant
Species: Guinea pig

Irritation Corrosion - Skin

TITANIUM DIOXIDE — Acute dermal irritation; OECD 404, Literature data
Result: Non-irritant
Species: Rabbit

Irritation Corrosion - Skin

TITANIUM DIOXIDE	Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human

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

Eye

NARATRIPTAN HYDROCHLORIDE	OECD 405 Result: Mild irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Respiratory sensitisation Not established.

Skin sensitisation

Sensitisation

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure Patch test, Literature data Result: negative Species: Human

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

Germ cell mutagenicity

Mutagenicity

NARATRIPTAN HYDROCHLORIDE	Ames Result: negative
TITANIUM DIOXIDE	Ames, Literature data Result: negative
NARATRIPTAN HYDROCHLORIDE	Bacterial High Throughput Fluctuation Test Result: negative Chromosomal Aberration Assay In Vitro Result: negative
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: positive
NARATRIPTAN HYDROCHLORIDE	Micronucleus Test Result: negative Species: Mouse Micronucleus Test Result: negative Species: Rat
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: negative
NARATRIPTAN HYDROCHLORIDE	WHO Nitrosation Assay Result: positive
TITANIUM DIOXIDE	WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: positive
NARATRIPTAN HYDROCHLORIDE	Yeast mutation Result: negative

Carcinogenicity Health injuries are not known or expected under normal use. Titanium Dioxide produced carcinogenic effects in a lifetime study in mice. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse

Carcinogenicity

TITANIUM DIOXIDE	10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months
NARATRIPTAN HYDROCHLORIDE	20 - 200 mg/kg/day oral Result: negative Species: Mouse 20 mg/kg/day Nitrite supplemented diet, NOAEL Species: Rat 20 mg/kg/day oral, NOAEL Result: negative Species: Rat
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
NARATRIPTAN HYDROCHLORIDE	90 mg/kg/day Nitrite supplemented diet Species: Rat Organ: thyroid Test Duration: 2 years 90 mg/kg/day oral, Species-specific Species: Rat Organ: thyroid Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Titanium dioxide (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductive toxicity

Reproductivity

NARATRIPTAN HYDROCHLORIDE	1 mg/kg/day Embryofetal Development Result: Decreased foetal weight, skeletal variations Species: Rabbit 10 mg/kg/day Pre- and Post-natal development Result: NOAEL Species: Rat 170 mg/kg/day Fertility, Male Result: NOAEL Species: Rat 30 mg/kg/day Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rabbit 340 mg/kg/day Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rat 340 mg/kg/day Fertility, Male Result: Effects on fertility, possible pre-implantation loss. Species: Rat 340 mg/kg/day Pre- and Post-natal development Result: NOAEL Species: Rat >= 10 mg/kg/day Embryofetal Development Result: incomplete/irregular ossification of skull bones, sternebrae, ribs Species: Rat >= 60 mg/kg/day Pre- and Post-natal development Result: foetal behavioural effects, decreased offspring viability and growth. Species: Rat

Specific target organ toxicity - single exposure Circulatory system.

Specific target organ toxicity - repeated exposure Testes.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Mixture versus substance information Not available.

Other information None known.

SECTION 12: Ecological information

12.1. Toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test results
NARATRIPTAN HYDROCHLORIDE (CAS 143388-64-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	100 - 1000 mg/l, 3 hours, OECD 209
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 100 mg/l, 72 hours, Static test, OECD 201
	NOEC	Green algae (Scenedesmus subspicatus)	100 mg/l, 72 hours, Static test
Crustacea	EC50	Water flea (Daphnia magna)	300 mg/l, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	160 mg/l, 48 hours, Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 100 mg/l, 96 hours, Static renewal test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours, Static renewal test
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static test

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

12.2. Persistence and degradability No data is available on the degradability of this product.

Persistence and degradability

Photolysis

UV/visible spectrum wavelength

NARATRIPTAN HYDROCHLORIDE 282.5 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

NARATRIPTAN HYDROCHLORIDE > 1 Years Calculated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

NARATRIPTAN HYDROCHLORIDE 27 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
3 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

NARATRIPTAN HYDROCHLORIDE < 1 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

NARATRIPTAN HYDROCHLORIDE 3 - 36 %, 64 days

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow)

NARATRIPTAN HYDROCHLORIDE 1.97

12.4. Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

NARATRIPTAN HYDROCHLORIDE 3.18 - 3.36 Measured

Mobility in general

Volatility

Henry's law

NARATRIPTAN HYDROCHLORIDE	0 atm m^3/mol, 25 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

NARATRIPTAN HYDROCHLORIDE	-0.62, pH 7 -1.7, pH 5 1.1, pH 9

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.

Always applicable.

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

Not regulated.

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	R22 Harmful if swallowed. R62 Possible risk of impaired fertility. R63 Possible risk of harm to the unborn child. H302 Harmful if swallowed. H361 Suspected of damaging fertility or the unborn child. H373 May cause damage to organs through prolonged or repeated exposure.
Revision information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients EXPOSURE CONTROLS/PERSONAL PROTECTION: Physical & Chemical Properties: Ecological Information: GSK Environmental Hazard Assessment Concentration TRANSPORT INFORMATION: Regulatory Information: United States
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.