



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	PARODONTAX ULTRA CLEAN
Registration number	-
Synonyms	MFC05486 * PARADONTAX ULTRA CLEAN 927PPM FLUORIDE * PARADONTAX ULTRA CLEAN TOOTHPASTE * SODIUM FLUORIDE, FORMULATED PRODUCT
Issue date	27-November-2020
Version number	01

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

Identified uses Oral Care

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

Company name	GlaxoSmithKline UK
Address:	980 Great West Road Brentford, Middlesex TW8 9GS UK
Telephone:	+44-20-8047-5000 (General Inquiries)
Email:	msds@gsk.com
Website:	www.gsk.com

EMERGENCY CONTACTS

Telephone:	VERISK 3E GLOBAL INCIDENT RESPONSE +(44) 20 35147487 or 0 800 680 0425 (In country) +(1) 760 476 3961 (International) 24/7; multi-language response
Contract Number:	334878

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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

Health hazards		
Skin sensitisation	Category 1	H317 - May cause an allergic skin reaction.

Hazard summary May cause an allergic skin reaction. Occupational exposure to the substance or mixture may cause adverse health effects. See section 11 of the SDS for additional information on health hazards.

2.2. Label elements

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

Contains: COCAMIDOPROPYL BETAINE, DODECYL SODIUM SULFATE, GLYCERIN, SODIUM BICARBONATE, Sodium fluoride, SPICY GINGERFREEZE FLAVOR

Hazard pictograms



Signal word	Warning
Hazard statements	
H317	May cause an allergic skin reaction.
Precautionary statements	
Prevention	
P261	Avoid breathing mist/vapours.
P264	Wash thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves.
Response	
P302 + P352	IF ON SKIN: Wash with plenty of water/.
P321	Specific treatment (see on this label).
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
Storage	Not available.
Disposal	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Supplemental label information	1.18 % of the mixture consists of component(s) of unknown acute oral toxicity. 70.44 % of the mixture consists of component(s) of unknown acute dermal toxicity. 77.79 % of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 76.61 % of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.
2.3. Other hazards	Assume that this material is capable of sustaining combustion. See section 11 of the SDS 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
SODIUM BICARBONATE	67.26	144-55-8 205-633-8	-	-	
Classification:	-				
GLYCERIN	9.35	56-81-5 200-289-5	-	-	
Classification:	-				
DODECYL SODIUM SULFATE	2	151-21-3 205-788-1	-	-	
Classification:	Flam. Sol. 2;H228, Acute Tox. 4;H302, Skin Irrit. 2;H315, Eye Dam. 1;H318, Acute Tox. 4;H332, STOT SE 3;H335, Aquatic Chronic 3;H412				
SPICY GINGERFREEZE FLAVOR	1.18	Unassigned -	-	-	
Classification:	Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Chronic 3;H412				
COCAMIDOPROPYL BETAINE	0.65	61789-40-0 263-058-8	-	-	
Classification:	Skin Irrit. 2;H315, Eye Irrit. 2;H319, Aquatic Acute 1;H400, Aquatic Chronic 2;H411				
Sodium fluoride	0.21	7681-49-4 231-667-8	-	009-004-00-7	#
Classification:	Acute Tox. 3;H301, Skin Irrit. 2;H315, Eye Irrit. 2;H319				
Other components below reportable levels	19.35				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).

M: M-factor

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. The need for pre-placement and periodic health surveillance must be determined by risk assessment.
4.1. Description of first aid measures	
Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. 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 advice from poison control center.
4.2. Most important symptoms and effects, both acute and delayed	None known.
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	Assume that this product is capable of sustaining combustion.
5.1. Extinguishing media	
Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist/vapours. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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	Use water spray to reduce vapours or divert vapour cloud drift. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. 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. Put material in suitable, covered, labeled containers.
6.4. Reference to other sections	For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Oral Care

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)	OHC	1	PROVISIONAL
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	1	>1000 - ≤5000 mcg/m3
SODIUM BICARBONATE (CAS 144-55-8)	OHC	1	>1000 - ≤5000 mcg/m3

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3	

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU, 2017/164/EU

Components	Type	Value
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls General ventilation normally adequate. 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.

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.
Eyeface protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166).
Skin protection	
- Hand protection	Not normally needed. 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	No personal respiratory protective equipment normally required. 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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Environmental exposure controls	
Hazard guidance and control recommendations	Good general ventilation 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Paste. Pump/tube.
Colour	Pink.
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 applicable.

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.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not established.

9.2. Other information

Percent volatile	18.2 % estimated
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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	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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Information on likely routes of 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. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms	None known.

11.1. Information on toxicological effects

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

Product	Species	Test Results
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PARODONTAX ULTRA CLEAN

Acute**Dermal**

LD50 Guinea pig 481 ml/kg estimated

Inhalation

LC50 Rat 2471 mg/l, 1 hour exposure estimated

Oral

LD50 Mouse 20100 mg/kg estimated

Rat 4429 mg/kg estimated

Other

LD50 Mouse 4691 mg/kg estimated

Rat 4179 mg/kg estimated

Components	Species	Test Results
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COCAMIDOPROPYL BETAINE (CAS 61789-40-0)

Acute**Oral**

LD50 Mouse > 2000 mg/kg

DODECYL SODIUM SULFATE (CAS 151-21-3)

Acute**Oral**

LD50 Rat 1288 mg/kg

GLYCERIN (CAS 56-81-5)

Acute**Oral**

LD50 Rat > 2000 mg/kg

SODIUM BICARBONATE (CAS 144-55-8)

Acute**Oral**

LD50 Rat
 >= 7300 mg/kg
 4220 - 8290 mg/kg

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. Direct contact with eyes may cause temporary irritation.
Respiratory sensitisation	No studies have been conducted.
Skin sensitisation	The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

IARC Monographs. Overall Evaluation of Carcinogenicity

Sodium fluoride (CAS 7681-49-4) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity - single exposure	Not assigned.
Specific target organ toxicity - repeated exposure	Not assigned.
Aspiration hazard	Not established.
Mixture versus substance information	No information available.
Other information	Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

12.1. Toxicity No data available for this product. Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	0.55 mg/l, 96 hours
	NOEC	Green algae (Scenedesmus subspicatus)	0.09 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	6.5 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	1.6 mg/l, 48 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	2 mg/l, 96 hours semi-static test conditions
	NOEC	Zebra fish (Adult Brachydanio rerio)	1.7 mg/l, 96 hours semi-static test conditions
Microtox	MIC	Pseudomonas	> 3000 mg/l, 16 hours
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	3.6 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0.9 mg/l, 21 days
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.6 mg/l, 96 hours flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-though Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days flow-through test
SODIUM BICARBONATE (CAS 144-55-8)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	650 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	2350 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	8250 - 9000 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	7550 mg/l, 96 hours Static test
Sodium fluoride (CAS 7681-49-4)			
Acute			
	IC50	Activated sludge	2930 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	272 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	340 mg/l, 48 hours Static test

Components	Species	Test Results
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)
		Mosquito fish (Adult Gambusia affinis)
		Rainbow trout (Juvenile Oncorhynchus mykiss)
		180 mg/l, 96 hours Static renewal test
		418 mg/l, 96 hours Static test
		108 mg/l, 96 hours Static test

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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

COCAMIDOPROPYL BETAINE 97 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
99 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Percent Degradation (Aerobic Biodegradation-Ready)

COCAMIDOPROPYL BETAINE 100 %, 20 Days Modified Sturm test., Activated sludge
84 %, 30 days Closed Bottle test, Activated sludge
DODECYL SODIUM SULFATE 95 % OECD 301 B

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient

n-octanol/water (log Kow)

DODECYL SODIUM SULFATE 1.6
GLYCERIN -1.76

Bioconcentration factor (BCF)

Sodium fluoride 2.3 Measured

12.4. Mobility in soil No data available.

Mobility in general Not available.

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). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. - 14.6.: Not regulated as dangerous goods.

RID

14.1. - 14.6.: Not regulated as dangerous goods.

ADN

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

Not available.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

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 and II, as amended

Not listed.

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

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 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, as amended

Sodium fluoride (CAS 7681-49-4)

Regulation (EC) No. 1907/2006, REACH Article 59(10) 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, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

According to Directive 92/85/EEC as amended, pregnant women should not work with the product, if there is the least risk of exposure.

Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended. Follow national regulation for work with chemical agents in accordance with Directive 98/24/EC, as amended.

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 H-statements not written out in full under Sections 2 to 15

H228 Flammable solid.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Revision information**Training information****Disclaimer**

H412 Harmful to aquatic life with long lasting effects.

None.

Follow training instructions when handling this material.

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.