



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 EXTRA FRESH TOOTHPASTE (1000PPM FLUORIDE) MFC04181
Registration number	-
Synonyms	PARODONTAX WHITENING TOOTHPASTE * MFC04181 * SODIUM FLUORIDE, FORMULATED PRODUCT
Issue date	08-November-2021
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

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Health hazards

Skin sensitisation	Category 1	H317 - May cause an allergic skin reaction.
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Hazard summary

May cause an allergic skin reaction. Dangerous for the environment if discharged into watercourses. 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:	CHAMOMILE OIL, CORNMINT OIL TERPENELESS, OPTAMINT POLAR FROST 822121, PEPPERMINT OIL, SAGE OIL
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Hazard pictograms



Signal word

Warning

Hazard statements

H317

The mixture does not meet the criteria for classification.
May cause an allergic skin reaction.

Precautionary statements

Prevention

P261

Avoid breathing mist/vapours.

P272

Contaminated work clothing should not be allowed out of the workplace.

P280

Wear protective gloves.

Response

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

1.248 % of the mixture consists of component(s) of unknown acute oral toxicity. 69.708 % of the mixture consists of component(s) of unknown acute dermal toxicity. 74.048 % of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 74.048 % of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment. EUH208 - Contains PEPPERMINT OIL, CORNMINT OIL TERPENELESS, CHAMOMILE OIL, SAGE OIL. May produce an allergic reaction.

2.3. Other hazards

Occupational Exposure Limits for constituents are listed in Section 8. 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
COCAMIDOPROPYL BETAINE	1.2	61789-40-0 263-058-8	-	-	
					Classification: Skin Irrit. 2;H315, Eye Irrit. 2;H319, Aquatic Acute 1;H400, Aquatic Chronic 2;H411
CORNMINT OIL TERPENELESS	0.963	68917-18-0	-	-	
					Classification: Acute Tox. 4;H302;(ATE: 1240 mg/kg), Skin Irrit. 2;H315, Eye Irrit. 2;H319, Skin Sens. 1;H317, Aquatic Chronic 2;H411
PEPPERMINT OIL	0.963	8006-90-4	-	-	
					Classification: Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411
CHAMOMILE OIL	0.624	Unassigned	-	-	
					Classification: Flam. Liq. 3;H226, Skin Sens. 1;H317, Asp. Tox. 1;H304, Aquatic Chronic 2;H411
OPTAMINT POLAR FROST 822121	0.5	Unassigned	-	-	
					Classification: Skin Irrit. 2;H315, Eye Irrit. 2;H319, Aquatic Chronic 3;H412
Sodium fluoride	0.221	7681-49-4 231-667-8	-	009-004-00-7	#
					Classification: Acute Tox. 3;H301;(ATE: 100 mg/kg), Skin Irrit. 2;H315, Eye Irrit. 2;H319
SAGE OIL	0.146	8016-64-6	-	-	
					Classification: Flam. Liq. 3;H226, Acute Tox. 4;H302, Skin Irrit. 2;H315, Skin Sens. 1;H317, STOT SE 2;H371, Asp. Tox. 1;H304, Aquatic Chronic 2;H411
Other components below reportable levels	95.383				

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 May cause an allergic skin reaction.

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 (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 Wear appropriate personal protective equipment.

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	Form
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)	OHC	1	>1000 - ≤5000 mcg/m3
	PDE	3000 mcg/day 10000 mcg/day	Parenteral, Inhalation Oral, Dermal
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.
Eye/face 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

Physical state Liquid.

Form Paste.
Pump/tube.

Colour Not available.

Odour Not available.

Melting point/freezing point Not available.

Boiling point or initial boiling point and boiling range Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Flash point Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

pH Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Particle characteristics Not available.

Other safety characteristics

Explosive properties Not explosive.

Oxidising properties Not established.

Percent volatile 19.3 % estimated

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.

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	May cause an allergic skin reaction.	
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		
CHAMOMILE OIL		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 5 g/kg
Oral		
LD50	Rat	> 5 g/kg
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)		
<u>Acute</u>		
Oral		
LD50	Mouse	> 2000 mg/kg
CORN MINT OIL TERPENELESS (CAS 68917-18-0)		
<u>Acute</u>		
Oral		
<i>Liquid</i>		
LD50	Rat	1240 mg/kg
PEPPERMINT OIL (CAS 8006-90-4)		
<u>Acute</u>		
Oral		
LD50	Rat	2426 mg/kg
Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Corrosivity		
PEPPERMINT OIL	Literature search Result: Positive	
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.	
Eye		
PEPPERMINT OIL	Literature search Result: Mild/moderate Irritant	
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.	
Sensitisation		
PEPPERMINT OIL	Literature search Result: Positive	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
CHAMOMILE OIL	Ames Assay Result: Negative	
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.	
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.

11.2. Information on other hazards

Endocrine disrupting properties Not 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			
<i>Acute</i>			
Algae	EC50	Green algae (<i>Scenedesmus subspicatus</i>)	0.55 mg/l, 96 hours
	NOEC	Green algae (<i>Scenedesmus subspicatus</i>)	0.09 mg/l, 96 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	6.5 mg/l, 48 hours
	NOEC	Water flea (<i>Daphnia magna</i>)	1.6 mg/l, 48 hours
Fish	EC50	Zebra fish (<i>Adult Brachydanio rerio</i>)	2 mg/l, 96 hours semi-static test conditions
	NOEC	Zebra fish (<i>Adult Brachydanio rerio</i>)	1.7 mg/l, 96 hours semi-static test conditions
Microtox	MIC	<i>Pseudomonas</i>	> 3000 mg/l, 16 hours
<i>Chronic</i>			
Crustacea	LOEC	Water flea (<i>Daphnia magna</i>)	3.6 mg/l, 21 days
	NOEC	Water flea (<i>Daphnia magna</i>)	0.9 mg/l, 21 days
Sodium fluoride (CAS 7681-49-4)			
<i>Acute</i>			
	IC50	Activated sludge	2930 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (<i>Selenastrum capricornutum</i>)	272 mg/l, 96 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	340 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (<i>Juvenile Pimephales promelas</i>)	180 mg/l, 96 hours Static renewal test
		Mosquito fish (<i>Adult Gambusia affinis</i>)	418 mg/l, 96 hours Static test
		Rainbow trout (<i>Juvenile Oncorhynchus mykiss</i>)	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

12.3. Bioaccumulative potential No data available for this product.

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. Endocrine disrupting properties Not available.
- 12.7. 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. UN number Not available.
- 14.2. UN proper shipping name Not available.
- 14.3. Transport hazard class(es)
- Class Not available.
- Subsidiary risk -
- 14.4. Packing group Not available.
- 14.5. Environmental hazards No.
- Special Provisions Not available

RID

- 14.1. UN number Not available.
- 14.2. UN proper shipping name Not available.
- 14.3. Transport hazard class(es)
- Class Not available.
- Subsidiary risk -
- 14.4. Packing group Not available.
- 14.5. Environmental hazards No.

ADN

- 14.1. UN number Not available.
- 14.2. UN proper shipping name Not available.
- 14.3. Transport hazard class(es)
- Class Not available.
- Subsidiary risk -
- 14.4. Packing group Not available.
- 14.5. Environmental hazards No.

IATA

- 14.1. UN number Not available.
- 14.2. UN proper shipping name Not available.
- 14.3. Transport hazard class(es)
- Subsidiary class(es) -
- 14.4. Packing group Not available.
- Labels required Not available.
- 14.5. Environmental hazards No.

IMDG

- 14.1. UN number Not available.
- 14.2. UN proper shipping name Not available.
- 14.3. Transport hazard class(es)
- Class Not available.
- Subsidiary risk -

14.4. Packing group Not available.

14.5. Environmental hazards

Marine pollutant No.

EmS Not available.

Not available.

14.7. Transport in bulk Not applicable.

**according to Annex II of
MARPOL73/78 and the IBC Code**

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 (EU) 2019/1021 On persistent organic pollutants (recast), 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**

H226 Flammable liquid and vapour.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H371 May cause damage to organs.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

Revision information

None.

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.