



PredictSURE IBD™ Safety Data Sheet

This Safety Data Sheet contains information concerning the potential risks to those involved in handling, transporting and working with the material, as well as describing potential risks to the consumer and the environment. This information must be made available to those who may come into contact with the material or are responsible for the use of the material.



SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

Product name	PredictSURE IBD™
Product code	Components of kit PI001 (PredictSURE IBD™ RT Enzyme Mix, PredictSURE IBD™ RT Reaction Mix, PredictSURE IBD™ GEX Mastermix, PredictSURE IBD™ Assay 1-17 (17 mixtures)).
Chemical family	Mixture
REACH registration number	No registration number is given yet for the substance/substances in the mixture components of this kit since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

Relevant identified uses of the substance or mixture

Relevant identified uses	For use together as in vitro diagnostic (IVD) assay, which is performed utilising RT-qPCR technology on whole blood samples from patients with a prior diagnosis of IBD, either Crohn's disease or ulcerative colitis.
Uses advised against	It should not be used for any other purpose.
Use Description Code	SU22 – Professional uses, PROC15 – Use as a laboratory reagent, PC21 – Laboratory chemicals
Details of the supplier of the safety data sheet	PredictImmune Limited Maia Building 270; Babraham Research Campus; Cambridge; CB22 3AT UK www.predictimmune.com Tel: +44(0)1223 804 195 E-mail: info@predictimmune.com
Emergency telephone number	Tel: +44(0)1223 804 195 (office hours only)

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SECTION 2 – HAZARDS IDENTIFICATION

Information relevant for all components of the kit (as stated in Section 1).

Classification of the substance or mixture	Classified according to Regulation (EC) No 1272/2008 (CLP).
Physical hazards	Not classified
Environmental hazards	Not classified
Other/Supplemental	None required
Label elements	Labelling according to Regulation (EC) No 1272/2008 (CLP)
Hazard pictogram	None required
Signal word	None required
Hazard statements	None required
Precautionary statements	None required
Other hazards	This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Information relevant for PredictSURE IBD™ RT Enzyme Mix and PredictSURE IBD™ RT Reaction Mix components.

Substances The product contains no substances, which at their given concentration are considered to be hazardous to health.

Chemical Name	CAS #	EINECS/ELINCS #	Amount percent	REACH registration number	Classification according to Regulation (EC) No 1272/2008 (CLP)
Glycerin	56-81-5	200-289-5	40 - 70	01-2119471987-18-XXXX	Not classified

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS . . . continued

Information relevant for PredictSURE IBD™ GEX Mastermix component

Substances The product contains no substances, which at their given concentration are considered to be hazardous to health.

Chemical Name	CAS #	EINECS/ELINCS #	Amount percent	REACH registration number	Classification according to Regulation (EC) No 1272/2008 (CLP)
Glycerin	56-81-5	200-289-5	10 - 30	01-2119471987-18-XXXX	Not classified

Information relevant for PredictSURE IBD™ Assay 1-17 mixture components

Substances The product contains no substances, which at their given concentration are considered to be hazardous to health.

Chemical Name	CAS #	EINECS/ELINCS #	Amount percent	REACH registration number	Classification according to Regulation (EC) No 1272/2008 (CLP)
Non-hazardous reagent(s)	--	--	--	--	--

SECTION 4 – FIRST AID MEASURES

Information relevant for all components of the kit (as stated in Section 1).

Description of first aid measures

Immediate medical attention needed	Immediate medical attention is not required. If concerned, get medical advice/attention.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Skin contact	Rinse with plenty of water.
Inhalation	Not expected to be an inhalation hazard under anticipated conditions of normal use. Consult medical advice if necessary.
Ingestion	Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.
Notes to Physician	Treat symptomatically.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	Not applicable.
Indication of immediate medical attention and special treatment needed, if necessary	None known or reported.

SECTION 5 – FIREFIGHTING MEASURES

Information relevant for all components of the kit (as stated in Section 1).

Extinguishing media	In case of fire in the surroundings: Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate.
Unsuitable extinguishing media	No information identified.
Specific hazards arising from the substance or mixture	Not known.
Flammability/Explosivity	No explosivity or flammability data identified. As product is primarily aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Information relevant for all components of the kit (as stated in Section 1).

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Environmental precautions	No special precautions required.
Methods and material for containment and cleaning up	For small spills, soak up with inert absorbent material, e.g., paper towels. For large spills, cordon off spill area to minimise the spreading of spilled material. Soak up with inert absorbent material. Wash spill area thoroughly with water if needed.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 – HANDLING AND STORAGE

Information relevant for all components of the kit (as stated in Section 1).

Precautions for safe handling	Use personal protective equipment as required. No special handling requirements are necessary.
Conditions for safe storage including any incompatibilities	Store unopened vials in a dry area at -20°C. Keep in properly labelled containers, upright, and tightly closed.
Specific end use(s)	For use as a laboratory reagent.

SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION

Information relevant for PredictSURE IBD™ RT Enzyme Mix, PredictSURE IBD™ RT Reaction Mix and PredictSURE IBD™ GEX Mastermix components.

Control Parameters/Occupational Exposure Limit Values

Exposure Limits

Chemical Name	EU OEL (TWA)	EU OEL (STEL)	EU Skin Notation	
Glycerin 56-81-5	None	None	None	
Chemical Name	Austria	Belgium (TWA)	Denmark (TWA)	Finland (TWA)
Glycerin 56-81-5	None	10 mg/m ³	None	None
Chemical Name	France OEL (VME)	Germany OEL (TWA)	Ireland (TWA)	Italy OEL (TWA)
Glycerin 56-81-5	10 mg/m ³	None	10 mg/m ³	None
Chemical Name	Sweden – Occupational Exposure Limits – TLVs (LLVs)	Netherlands OEL (MAC)	Spain OEL	United Kingdom
Glycerin 56-81-5	None	None	10 mg/m ³	10 mg/m ³
Chemical Name	European Union	United Kingdom	France OEL (VME)	Germany OEL (TWA)
Glycerin 56-81-5	None	None	10 mg/m ³	10 mg/m ³
Chemical Name	Italy OEL (TWA)	Portugal	Netherlands OEL (MAC)	Finland OEL (TWA)
Glycerin 56-81-5	None	None	None	None
Chemical Name	Austria	Denmark	Poland	Switzerland
Glycerin 56-81-5	None	None	None	None
Chemical Name	Ireland	Norway	Lithuania (OEL (TWA))	Spain OEL (TWA)
Glycerin 56-81-5	None	None	None	10 mg/m ³

SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION . . . continued**Information relevant for PredictSURE IBD™ RT Enzyme Mix, PredictSURE IBD™ RT Reaction Mix and PredictSURE IBD™ GEX Mastermix components**

Engineering controls	Ensure adequate ventilation, especially in confined areas. Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential.
Exposure controls	
Respiratory protection	In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.
Hand protection	Wear nitrile or other impervious, compatible, chemical-resistant gloves.
Skin and body protection	Wear suitable protective clothing. Base the choice of skin protection (e.g., appropriate gloves, lab coat, or other protective overgarment) on the job activity, potential for skin contact and solvents and reagents in use.
Eye/face protection	Tight sealing safety goggles. Base the choice of protection (e.g., chemical splash goggles) on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental Exposure Controls	No special precautions required. Avoid discharge into drains and waterways whenever possible.
Other protective measures	Protective equipment is not to be worn outside the work area (e.g. in common areas or out-of-doors).

SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION . . . continued

Information relevant for PredictSURE IBD™ Assay 1-17 mixture components

Chemical Name	Issuer	Type	OEL
Non-Hazardous Reagent(s)	--	--	--

Engineering controls	No specific controls or precautions required. Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential.
Exposure controls	
Respiratory protection	No special precautions required. Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls.
Hand protection	No special precautions required. Wear nitrile or other impervious, compatible, chemical-resistant gloves.
Skin and body protection	No special precautions required. Wear suitable protective clothing. Base the choice of skin protection (e.g., appropriate gloves, lab coat, or other protective overgarment) on the job activity, potential for skin contact and solvents and reagents in use.
Eye/face protection	Tight sealing safety goggles. Base the choice of protection (e.g., chemical splash goggles) on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental Exposure Controls	No special precautions required. Avoid discharge into drains and waterways whenever possible.
Other protective measures	Protective equipment is not to be worn outside the work area (e.g. in common areas or out-of-doors).

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Information is relevant to PredictSURE IBD™ RT Enzyme Mix, PredictSURE IBD™ RT Reaction Mix and PredictSURE IBD™ Assay 1-17 mixture components

Information on basic physical and chemical properties

Appearance	Liquid
Colour	Clear
Odour	No information identified.
Odour threshold	No information identified.
pH	Mixture has not been tested.
Melting point / melting range	°C No information identified °F No information identified
Boiling point / boiling range	°C No information identified °F No information identified
Flash point	°C No information identified °F No information identified
Auto-ignition temperature	°C No information identified °F No information identified
Decomposition temperature	°C No information identified °F No information identified
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper flammability explosive limit	Mixture has not been tested.
Lower flammability explosive limit	Mixture has not been tested.
Vapour pressure	Mixture has not been tested.
Relative density	Mixture has not been tested.
Specific gravity	No information identified.
Solubility	No information identified.
Partition coefficient (n-octanol/water)	No information identified.
Viscosity	No information identified.
Explosive properties	Mixture has not been tested.
Oxidizing properties	No information identified.
Other information	
Molecular weight	Not applicable (Mixture)
Molecular formula	Not applicable (Mixture)

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES . . . continued

Information is relevant for PredictSURE IBD™ GEX Mastermix component

Information on basic physical and chemical properties

Appearance	Liquid	
Colour	Clear	
Odour	No information identified.	
pH	Mixture has not been tested.	
Melting point / melting range	°C >0	°F >32
Boiling point / boiling range	°C >100	°F >212
Flash point	°C >90	°F >160
Auto-ignition temperature	°C Mixture has not been tested	°F Mixture has not been tested
Decomposition temperature	°C Mixture has not been tested	°F Mixture has not been tested
Evaporation rate	No information identified.	
Flammability (solid, gas)	No information identified.	
Upper flammability explosive limit	Mixture has not been tested.	
Lower flammability explosive limit	Mixture has not been tested.	
Vapour pressure	Mixture has not been tested.	
Relative density	Mixture has not been tested.	
Specific gravity	No information identified.	
Solubility	Soluble in water.	
Partition coefficient (n-octanol/water)	No information identified.	
Explosive properties	Mixture has not been tested.	
Other information		
Molecular weight	Not applicable (Mixture)	
Molecular formula	Not applicable (Mixture)	

SECTION 10 – STABILITY AND REACTIVITY

Information is relevant for PredictSURE IBD™ RT Enzyme Mix and PredictSURE IBD™

RT Reaction Mix components

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to avoid	No information identified.
Incompatible materials	No dangerous reaction known under conditions of normal use.
Hazardous decomposition	No information identified.

Information is relevant for PredictSURE IBD™ GEX Mastermix component

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to avoid	None under normal processing.
Incompatible materials	Strong acids, oxidising agents, acetic anhydride, isocyanates, ammonia, bases.
Hazardous decomposition	Carbon oxides.

Information is relevant for PredictSURE IBD™ Assay 1-17 mixture components

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to avoid	High temperature. Thermal decomposition of the finish can take place about (>140 °C) >284 °C
Incompatible materials	Oxidising agents, acids, bases, sulphur trioxide, iodine.
Hazardous decomposition	No information identified.

SECTION 11 – TOXICOLOGICAL INFORMATION

Information relevant for PredictSURE IBD™ RT Enzyme Mix, PredictSURE IBD™ RT reaction mix and PredictSURE IBD™ GEX Mastermix components

Information on toxicological effects

Acute toxicity

Chemical Name	LD50 (oral, rat/mouse)	LD50 (dermal, rat/rabbit)	LC50 (inhalation, rat/mouse)
Glycerin	= 12600 mg/kg oral	No data available	>570mg/m ³ (rat)

Principle Routes of Exposure, Potential health effects

Route of entry	May be absorbed by inhalation and ingestion. No information on skin contact absorption identified.
Irritation/Corrosion	Conclusive but not sufficient for classification.
Sensitisation	Conclusive but not sufficient for classification.
STOT-single exposure	Conclusive but not sufficient for classification.
STOT-repeated exposure/Repeat-dose toxicity	Conclusive but not sufficient for classification.
Carcinogenicity	Conclusive but not sufficient for classification.
Mutagenicity	Conclusive but not sufficient for classification.
Reproductive toxicity	Conclusive but not sufficient for classification.

Information relevant for PredictSURE IBD™ Assay 1-17 mixture components

Information on toxicological effects

No data available for this mixture. The hazards may be similar to the hazards of the ingredient(s), all of which are considered non-hazardous.

Route of entry	May be absorbed by inhalation and ingestion. No information on skin contact absorption identified.
Irritation/Corrosion	No data on product formulation.
Sensitisation	No data on product formulation.
STOT-single exposure	No data on product formulation.
STOT-repeated exposure/Repeat-dose toxicity	No data on product formulation.
Carcinogenicity	No data on product formulation.
Mutagenicity	No data on product formulation.
Reproductive toxicity	No data on product formulation.
Aspiration hazard	No data on product formulation.

SECTION 12 – ECOLOGICAL INFORMATION

Information relevant for PredictSURE IBD™ RT Enzyme Mix and PredictSURE IBD™

RT Reaction Mix components

Toxicity Ecological characteristics of this mixture were not available.

Ingredient	Freshwater Algae Data	Water Flea Data	Freshwater Fish Species Data	Microtox Data	Log Pow
Glycerin	No data available	No data available	No data available	No data available	logPow-1.76

Persistence and Degradability

No information identified.

Bioaccumulative potential

No information identified.

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other adverse effects

No information identified.

Information relevant for PredictSURE IBD™ GEX Mastermix component

Toxicity Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.

Ingredient	Freshwater Algae Data	Water Flea Data	Freshwater Fish Species Data	Microtox Data	Log Pow
Glycerin	No data available	Daphnia magna EC50>500 mg/L (24h)	No data available	No data available	logPow-1.76

Persistence and Degradability

Inherently biodegradable.

Bioaccumulative potential

Material does not bioaccumulate.

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other adverse effects

No information identified.

SECTION 12 – ECOLOGICAL INFORMATION . . . continued

Information relevant for PredictSURE IBD™ Assay 1-17 mixture components

Toxicity	The environmental impact of this product has not been fully investigated.
Persistence and Degradability	Readily biodegradable.
Bioaccumulative potential	Material does not bioaccumulate.
Results of PBT and vPvB assessment	This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
Other adverse effects	No information identified.

SECTION 13 – DISPOSAL CONSIDERATIONS

Information relevant for all components of the kit (as stated in Section 1).

Waste treatment methods	The generation of waste should be avoided or minimised wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in accordance with approved disposal techniques. Disposal of this product, its solutions or of any by-products, should comply with the requirements of all applicable local, regional or national/federal regulations.
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SECTION 14 – TRANSPORT INFORMATION

Information relevant for all components of the kit (as stated in Section 1).

Transport	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under ADR, US DOT, IATA, or IMDG.
UN number	Not applicable.
UN proper shipping name	Not applicable.
Transport hazard class(es)	Not applicable.
Packing group	Not applicable.
Environmental hazards	Not applicable.
Special precautions for users	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 – REGULATORY INFORMATION

Information relevant for PredictSURE IBD™ RT Enzyme Mix and PredictSURE IBD™ RT Reaction Mix components

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

Chemical safety assessment	Not conducted.
Substances of Very High Concern	None
Restricted substances under EC 1907/2006, Annex XVII	None
Substances listed under Annex I of Regulation (EC) No 689/2008	None
Restricted substances under Annex V of Regulation (EC) No 689/2008	None
Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC	None

German Water hazard classes (Wassergefährdungsklassen)

Chemical Name	Weight percent	Germany – Water Classification (VwVwS) Annex 1 – Water Hazard Classes	Germany – Water Classification (VwVwS) Annex 2 – Water Hazard Classes	Germany – Water classification (VwVwS) – Annex 3
Glycerin	40-70	--	hazard class 1 – low hazard to waters	--

SECTION 15 – REGULATORY INFORMATION . . . continued
Other International Inventories

Chemical Name	EINECS (European Union)	EINECS (European List of Notified Chemical Substances)	ENCD (Japan)	PICCS (Philippines)
Glycerin	Listed	--	Listed	--

Chemical Name	AICS (Australia)	South Korea (KECL)	Canada (DSL)	NDSL
Glycerin	Listed	Listed	Listed	--

Information relevant for PredictSURE IBD™ GEX Mastermix component
Safety, health and environmental regulations/legislation specific for the substance or mixture

Chemical safety assessment	Not conducted.
Substances of Very High Concern	None
Restricted substances under EC 1907/2006, Annex XVII	None
Substances listed under Annex I of Regulation (EC) No 689/2008	None
Restricted substances under Annex V of Regulation (EC) No 689/2008	None
Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC	None

SECTION 15 – REGULATORY INFORMATION . . . continued
German Water hazard classes (Wassergefährdungsklassen)

Chemical Name	Weight percent	Germany – Water Classification (VwVwS) Annex 1 – Water Hazard Classes	Germany – Water Classification (VwVwS) Annex 2 – Water Hazard Classes	Germany – Water classification (VwVwS) – Annex 3
Glycerin	10-30	--	hazard class 1 – low hazard to waters	--

Other International Inventories

Chemical Name	EINECS (European Union)	EINECS (European List of Notified Chemical Substances)	ENCD (Japan)	PICCS (Philippines)
Glycerin	Listed	--	Listed	Listed

Chemical Name	AICS (Australia)	South Korea (KECL)	Canada (DSL)	NDSL
Glycerin	Listed	Listed	Listed	--

SECTION 15 – REGULATORY INFORMATION . . . continued**Information relevant for PredictSURE IBD™ Assay 1-17 mixture components****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Chemical safety assessment	Not conducted.
Substances of Very High Concern	None
Restricted substances under EC 1907/2006, Annex XVII	None
Substances listed under Annex I of Regulation (EC) No 689/2008	None
Restricted substances under Annex V of Regulation (EC) No 689/2008	None
Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC	None

SECTION 16 – OTHER INFORMATION

Full text of R phrases and EU Classifications	Not applicable.
Full text of H phrases and GHS classifications	Not applicable.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labelling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Issue Date	07 JAN 2019
Revisions	V-02 Updated to reflect PredictSURE IBDTM branding (CC-18-74). V-01 This is the first versions of this safety data sheet (CC-18-70)
Disclaimer	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/ diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.