



# PredictSURE IBD™ quality control 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™ Quality Control

**Product code** PI002

**Chemical family** Mixture

**REACH registration number** No registration number is given yet for the substance/substances in this mixture 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 as quality control material, with the PredictSURE IBD™ Assay kit; an 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

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**Issue Date** 07 JAN 2019

## SECTION 2 – HAZARDS IDENTIFICATION

<b>Classification of the substance or mixture</b>	This mixture is not classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA).
<b>Physical hazards</b>	Not hazardous
<b>Environmental hazards</b>	Not hazardous
<b>Other/Supplemental</b>	Mixture not yet fully tested
<b>Label elements</b>	
<b>Hazard pictogram</b>	None required
<b>Signal word</b>	None required
<b>Hazard statements</b>	None required
<b>Precautionary statements</b>	None required
<b>Other hazards</b>	The hazardous properties of this mixture have not been fully investigated. Potential health hazards associated with exposure/handling may be similar to the ingredients, all of which are considered non-hazardous (See Section 3).

## SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

<b>Substances</b>	The principal ingredient in this mixture is distilled water. Any remaining components are not hazardous and/or are present at amounts below reportable limits. The classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.
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Chemical Name	CAS #	EINECS/ELINCS #	Amount percent	Classification according to Regulation (EC) No 1272/2008 (CLP) and Hazard Communication Standard No. 1910.1200
Non-Hazardous Reagent(s)	N/A	N/A	~100	Not classified

## SECTION 4 – FIRST AID MEASURES

### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	None. If exposed or concerned: Get medical advice/attention.
<b>Eye Contact</b>	Flush with water. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	No specific first aid measures required. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	No specific first aid measures required. In case of accidental inhalation, move exposed subject to fresh air. If signs/symptoms occur or if concerned, get medical attention.
<b>Ingestion</b>	No specific first aid measures required. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. If signs/symptoms occur or if concerned, get medical attention.
<b>Notes to Physician</b>	Treat symptomatically.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11.
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	None known or reported.

## SECTION 5 – FIREFIGHTING MEASURES

<b>Extinguishing media</b>	In case of fire in the surroundings: use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate.
<b>Unsuitable extinguishing Media</b>	No information identified.
<b>Specific hazards arising from the substance or mixture</b>	No information identified.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. As product is primarily an aqueous solution, it is not expected to be flammable or explosive.
<b>Advice for firefighters</b>	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

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Environmental precautions</b>	No special precautions required.
<b>Methods and material for containment and cleaning up</b>	For small spills, soak up with absorbent material, e.g., paper towels. For large spills, cordon off spill area to minimise the spreading of spilled material. Soak up with absorbent material. Wash spill area thoroughly with water if needed.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

## SECTION 7 – HANDLING AND STORAGE

<b>Precautions for safe handling</b>	Use personal protective equipment as required. No special handling requirements are necessary for the normal use of this mixture.
<b>Conditions for safe storage including any incompatibilities</b>	Store unopened vials at -70°C in a dry and well-ventilated area, away from incompatible materials. Keep in properly labelled container, upright, and tightly closed.
<b>Specific end use(s)</b>	For use as a laboratory reagent.

## SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION

### Control Parameters/Occupational Exposure Limit Values

Chemical Name	Issuer	Type	OEL
Non-Hazardous Reagent(s)	--	--	--
<b>Engineering controls</b>	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.		
<b>Exposure controls</b>			
<b>Respiratory protection</b>	No special precautions required. Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls.		
<b>Hand protection</b>	No special precautions required. Wear nitrile or other impervious, compatible, chemical-resistant gloves to avoid mixture contamination.		
<b>Skin and body protection</b>	No special precautions required. 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.		
<b>Eye/face protection</b>	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.		

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

<b>Hygiene measures</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Environmental Exposure Controls</b>	No special precautions required.
<b>Other protective measures</b>	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 on basic physical and chemical properties

<b>Appearance</b>	Liquid
<b>Colour</b>	Clear
<b>Odour</b>	No information identified.
<b>Odour threshold</b>	No information identified.
<b>pH</b>	No information identified.
<b>Melting point/freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapour pressure</b>	No information identified.
<b>Vapour density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Specific gravity</b>	No information identified.
<b>Water solubility</b>	Miscible in water.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES . . . continued

<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	No applicable (Mixture)
<b>Molecular formula</b>	No applicable (Mixture)

## SECTION 10 – STABILITY AND REACTIVITY

<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	No information identified.
<b>Possibility of hazardous Reactions</b>	None expected to occur.
<b>Conditions to avoid</b>	Avoid excessive heat.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition</b>	No information identified.

## SECTION 11 – TOXICOLOGICAL INFORMATION

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

### Acute toxicity

Chemical Name	Type	Route	Species	Dose
Non-hazardous Reagent(s)	--	--	--	--

### Principle Routes of Exposure, Potential health effects

<b>Route of entry</b>	May be absorbed by inhalation, skin contact and ingestion.
<b>Irritation/Corrosion</b>	No data on product formulation.
<b>Sensitisation</b>	No data on product formulation.
<b>STOT-single exposure</b>	No data on product formulation.
<b>STOT-repeated exposure/ Repeat-dose toxicity</b>	No data on product formulation.
<b>Reproductive toxicity</b>	No data on product formulation.
<b>Developmental toxicity</b>	No data on product formulation.
<b>Genotoxicity</b>	No data on product formulation.

## SECTION 11 – TOXICOLOGICAL INFORMATION . . . continued

<b>Carcinogenicity</b>	No data on product formulation. None of the components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
<b>Mutagenicity</b>	No data on product formulation.
<b>Aspiration hazard</b>	No data on product formulation.
<b>Human health data</b>	See 'Section 2 – Other Hazards'

## SECTION 12 – ECOLOGICAL INFORMATION

<b>Toxicity</b>	Ecological characteristics of this mixture were not available. No special precautions needed.
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Compound	Type	Species	Concentration
Non-Hazardous Reagent(s)	--	--	--

<b>Persistence and Degradability</b>	No information identified.
<b>Bioaccumulative potential</b>	No information identified.
<b>Mobility in soil</b>	No information identified.
<b>Results of PBT and vPvB Assessment</b>	Not performed.
<b>Other adverse effects</b>	No information identified.

## SECTION 13 – DISPOSAL CONSIDERATIONS

<b>Waste treatment methods</b>	The generation of waste should be avoided or minimised wherever possible. Empty containers or liners may retain some product residues. No specific waste treatment methods are required. 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

<b>Transport</b>	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
<b>UN number</b>	None assigned.
<b>UN proper shipping name</b>	None assigned.
<b>Transport hazard classes</b>	None assigned.
<b>Packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	No special precautions needed.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## SECTION 15 – REGULATORY INFORMATION

<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>WHMIS classification</b>	This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all of the information required by those regulations.
<b>TSCA status</b>	Not listed.
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	No listed.
<b>Additional information</b>	No other information identified.

## SECTION 16 – OTHER INFORMATION

<b>Full text of R phrases and EU Classifications</b>	Not applicable.
<b>Full text of H phrases and GHS classifications</b>	Not applicable.
<b>Sources of data</b>	Information from published literature and internal company data.
<b>GHS classifications</b>	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA –

**SECTION 16 – OTHER INFORMATION . . . continued**

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 IBD™ 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.