SAFETY DATA SHEET

FOB One Step Fecal Occult Blood Test Device (ABON)

According to Regulation (EU) No. 2020/878

This document contains SDS for the following kit components:
Device
Buffer

Section 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Identification on the label/Trade name:	**FOB One Step Fecal Occult Blood Test Device**
Additional identification:	**Reference No.: TFO-602、TFO-602M**
Identification of the product:	See section 3
Index Number:	Not available
REACH registration No.:	Not available

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

1.2.1 Identified uses:

In vitro diagnostic reagent. For professional use only.

1.2.2 Uses advised against:

Not available.

1.3 Details of the supplier of the safety data sheet:

Supplier(Manufacturer):	Abon Biopharm (Hangzhou) Co., Ltd
Address:	#198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China
Contact person(E-mail):	ml-HNZ-interRA@abbott.com
Telephone:	+ 86-571-81638052
Fax:	+ 86-571-81638001

1.4 Emergency telephone Number:

+86-571-81638052

Available outside office hours?	YES		NO	X

Section 2 Hazards Identification

2.1 Classification of the substance or mixture:

2.1.1 Classification:

The mixture is classified as following according to REGULATION (EC) No 1272/2008:

REGULATION (EC) No 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

2.1.2 Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2 Lelements:

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard Pictograms (CLP): No hazard pictogram is used.

Signal Word(S) (CLP): No signal word is used.

Hazard Statement (CLP): Not applicable.

Precautionary statement (CLP): Not applicable.

EUH-statements： EUH032 - Contact with acids liberates very toxic gas.

2.3 Other hazards:

Other hazards which do not result in classification : No information available.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with (EC) No. 1907/2006for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Component	
Triton™ X-405 solution-70% in H2O(9036-19-5)	The substance is included in the list established in accordance with (EC) No. 1907/2006 for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Section 3 Composition/information on ingredients

3.1 Substance: Not applicable

3.2 Mixtures:

Chemical Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Triton™ X-405 solution-70% in H2O substance listed as REACH Candidate substance listed in REACH Annex XIV (4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues))	CAS-No.: 9036-19-5 EC-No.: 618-541-1	< 0.1	Acute tox. 4: H302

Full text of H- and EUH-statements: see section 16

Section 4 First aid measures

4.1 Description of first aid measures:

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip. In all cases of doubt, or when symptoms persist, seek medical attention.

4.1.1 In case of inhalation:

If inhalation, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

4.1.2 In case of skin contact:

Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

4.1.3 In case of eyes contact:

Flush with running water for at least 15 minutes. If irritation persists get medical attention.

4.1.4 In case of ingestion:

Rinse mouth with water. Obtain medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed:

No additional information available

4.3 Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

Section 5 Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media: Use extinguishing agents appropriate for surrounding fire.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance or mixture：

Fire hazard: Non-flammable.

Hazardous decomposition products in case of fire: Toxic fumes may be released.

5.3 Advice for firefighters：

Firefighting instructions： Approach from upwind. Complete protective clothing. Cool containers / tanks with spray water if possible. Eliminate all ignition sources if safe to do so.

Protection during firefighting： Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: Provide adequate ventilation. Avoid inhalation of dust. Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.

6.1.2 For emergency responders: Wear an appropriate NIOSH/MSHA approved respirator if dust is generated.

6.2 Environmental Precautions: Do not allow material to be released to the environment without proper governmental permits.

6.3 Methods and material for Containment and Cleaning up:

Methods for cleaning up： Pick up and transfer to properly labelled containers. Place in an appropriate container and dispose of the contaminated material at a licensed site.

Other information： Dispose of materials or solid residues at an authorized site.

6.4 Reference to other sections: See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

6.5 Additional information: Not applicable.

Section 7 Handling and storage

7.1 Precautions for safe handling:

7.1.1 Protective measures: Ensure good ventilation of the work station. Wear personal protective equipment.

7.1.2 Advice on general occupational hygiene: Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities: Material should be stored in a clean, dry environment at 2 to 30°C in original packaging and not exposed to ignition sources.

7.3 Specific end use(s): Use as per instructions for use.

Section 8 Exposure Controls/Personal Protection

8.1 Control parameters:

8.1.1 National occupational exposure and biological limit values No additional information available.

8.1.2Recommended monitoring procedures: No additional information available.

8.1.3Air contaminants formed : Not additional information available.

8.1.4 DNEL and PNEC-Values: No additional information available.

8.1.5. Control banding: No additional information available.

8.2 Exposure controls:

8.2.1Appropriate engineering controls: Ensure good ventilation of the work station.

8.2.2 Individual protection measures, such as personal protective equipment:

8.2.2.1 Eye/face protection:

Eye protection:	Safety glasses.
Face protection:	No special protective equipment required.

8.2.2.2 Skin protection:

Skin and body protection:	Wear suitable protective clothing.
Hand Protection:	Protective gloves.

8.2.2.3 Respiratory protection:	In case of insufficient ventilation, wear suitable respiratory equipment
8.2.2.4 Thermal hazards:	No additional information available
8.2.3 Environmental exposure controls:	Avoid discharge into the environment. According to local regulations, Federal and official regulations.

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:	Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents. The test strip is housed in a plastic cassette.
Physical state：	Test strip
Colour:	White.
Odour:	No odour.
Odour threshold:	Not available
pH:	Not available
pH solution：	Not available
Solubility：	Not available
Partition coefficient n-octanol/water (Log Kow)：	Not available
Melting point/range (°C):	Not available
Freezing point：	Not available
Boiling point/range (°C):	Not available
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (solid, gas):	Not available
Ignition temperature (°C):	Not available
Upper/lower flammability/explosive limits:	Not available
Vapour pressure	Not available
Vapour pressure (20°C):	Not available
Vapour density:	Not available
Density:	Not available
Relative Density:	Not available

Relative vapour density at 20 °C:	Not available
Bulk density (kg/m^3):	Not available
Water solubility (g/l):	Not available
n-Octanol/Water (log Po/w):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity, dynamic (mPa.s):	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
Molecular Formula:	Not available
Molecular Weight:	Not available
Particle size:	Not available
Particle size distribution:	Not available
Particle shape:	Not available
Particle aspect ratio:	Not available
Particle aggregation state:	Not available
Particle agglomeration state:	Not available
Particle specific surface area:	Not available
Particle dustiness:	Not available

9.2. Other information:

9.2.1. Information with regard to physical hazard classes

Fat solubility(solvent– oil to be specified)	Not available
etc:	
Surface tension:	Not available
Dissociation constant in water(pKa):	Not available
Specific gravity:	Not available

9.2.2. Other safety characteristics

Oxidation-reduction Potential:	Not available

Section 10 Stability and reactivity

10.1 Reactivity:	The substance is stable under normal storage and handling conditions.
10.2 Chemical stability:	Stable at 2 to 30°C in closed containers under normal storage and handling conditions.
10.3 Possibility of hazardous reactions:	No dangerous reactions known.
10.4 Conditions to avoid:	Incompatible materials.
10.5 Incompatible materials:	No information available
10.6 Hazardous decomposition products:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) Not classified

Acute toxicity (dermal) Not classified

Acute toxicity (inhalation) Not classified

Triton™ X-405 solution-70% in H2O (9036-19-5)	
LD50 oral rat	1700 mg/kg

Skin corrosion/Irritation: Not classified

Serious eye damage/irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

STOT- single exposure: Not classified

STOT-repeated exposure: Not classified

Aspiration hazard: Not classified

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties The mixture does not contain substance(s) included in the list established in accordance with (EC) No. 1907/2006 for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

Section 12 Ecological information

12.1 Toxicity:

Ecology – general： The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute)： Not classified

Hazardous to the aquatic environment, long-term (chronic)： Not classified

12.2 Persistence and degradability: Not available.

12.3 Bioaccumulative potential: Not available.

12.4 Mobility in soil: Not available.

12.5 Results of PBT&vPvB assessment: Not available.

12.6 Endocrine disrupting properties

Component	
Triton™ X-405 solution-70% in H2O(9036-19-5)	Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

12.7 Other adverse effects: Not available.

Section 13 Disposal considerations

13.1 Waste treatment methods: The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional

13.2 Product / Packaging disposal: If empty container retains product residues, all label precautions must be observed. Dispose according to national or local regulations.

Section 14 Transport information

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6 Special precautions for user

Overland transport: Not regulated

Transport by sea: Not regulated

Air transport: Not regulated

Inland waterway transport: Not regulated

Rail transport: Not regulated

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

Section 15 Regulation information

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

15.1.1. EU-Regulations

- Contains no REACH substances with Annex XVII restrictions
- Contains REACH Annex XIV substances: Triton™ X-405 solution-70% in H2O (EC 618-541-1, CAS 9036-19-5)
- Contains a substance on the REACH candidate list: Triton™ X-405 solution-70% in H2O (EC 618-541-1, CAS 9036-19-5)
- Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.
- Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
- Contains no substance subject to (EC) No. 1907/2006 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.
- Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on drug precursors)

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out.

Section 16 Other information

16.1 Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

16.2 Data sources: ECHA (European Chemicals Agency). Loli.

16.3 Training advice： Normal use of this product shall imply use in accordance with the instructions on the packaging.

16.4 Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.

16.5 Indication of changes:

Version AF Amended by EU 2020/878

16.6 Relevant R- phrases (number and full text):

Not applicable.

16.7 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

16.8 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

Section 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Identification on the label/Trade name: **Buffer of FOB One Step Fecal Occult Blood Test Device**

Additional identification: **Reference No.: TFO-602、TFO-602M**

Identification of the product: See section 3

Index Number: Not available

REACH registration No.: Not available

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

1.2.1 Identified uses:

Buffer for use with FOB One Step Fecal Occult Blood Test Device.

1.2.2 Uses advised against:

For professional in vitro diagnostic use only.

1.3 Details of the supplier of the safety data sheet:

Supplier(Manufacturer): Abon Biopharm (Hangzhou) Co., Ltd

Address: #198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China

Contact person(E-mail): ml-HNZ-interRA@abbott.com

Telephone: + 86-571-81638052

Fax: + 86-571-81638001

1.4 Emergency telephone Number:

+86-571-81638052

Available outside office hours? YES [ ] NO [X]

Section 2 Hazards Identification

2.1 Classification of the substance or mixture:

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Skin sensitisation, category 1A	H317

Full text of H- and EUH-statements: see section 16

2.1.2 Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2 Label elements:

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard Pictograms (CLP):

GHS07

Signal Word(S) (CLP): Warning

Hazard Statement (CLP):

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

Precautionary statement (CLP):

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 - Wash hands, forearms and face thoroughly after handling.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

EUH-statements:

EUH032 - Contact with acids liberates very toxic gas.

EUH071 - Corrosive to the respiratory tract.

2.3 Other hazards:

Other hazards which do not result in classification: No information available.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with (EC) No. 1907/2006 for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

Section 3 Composition/information on ingredients

3.1 Substance: Not applicable

3.2 Mixtures :

Chemical Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethoxylated acetylenic diols	CAS-No.: 9014-85-1 EC-No.: 500-022-5	0.5	Eye Dam. 1, H318 Skin Sens. 1B, H317 Aquatic Chronic 3, H412
ProClin™ 300	CAS-No.: 55965-84-9 EC-No.: 611-341-5;911-418-6 EC Index-No.: 613-167-00-5	< 0.1	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1C, H314

			Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 EUH071

Specific concentration limits:		
Chemical Name	**Product identifier**	**Specific concentration limits**
ProClin™ 300	CAS-No.: 55965-84-9 EC-No.: 611-341-5;911-418-6 EC Index-No.: 613-167-00-5	(0.0015 ≤C < 100) Skin Sens. 1A, H317 (0.06 ≤C < 0.6) Eye Irrit. 2, H319 (0.06 ≤C < 0.6) Skin Irrit. 2, H315 (0.6 ≤C < 100) Skin Corr. 1C, H314 (0.6 ≤C < 100) Eye Dam. 1, H318

Full text of H- and EUH-statements: see section 16

Section 4 First aid measures

4.1 Description of first aid measures:

In all cases of doubt, or when symptoms persist, seek medical attention.

4.1.1 In case of inhalation:

If inhalation, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

4.1.2 In case of skin contact:

Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

4.1.3 In case of eyes contact:

Flush with running water for at least 15 minutes. If irritation persists get medical attention.

4.1.4 In case of ingestion:

Rinse mouth with water. Obtain medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed:

No additional information available.

4.3 Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

Section 5 Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media: Use extinguishing agents appropriate for surrounding fire.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance or mixture

Fire hazard： Non-flammable

Hazardous decomposition products in case of fire： Toxic fumes may be released.

5.3 Advice for firefighters

Firefighting instructions： Approach from upwind. Complete protective clothing. Cool containers /

tanks with spray water if possible. Eliminate all ignition sources if safe to do so.

Protection during firefighting： Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: Provide adequate ventilation. Avoid inhalation of vapours. Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.

6.1.2 For emergency responders: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

6.2 Environmental Precautions: Do not allow material to be released to the environment without proper governmental permits.

6.3 Methods for Containment and Cleaning up:

Methods for cleaning up： Absorb remaining liquid with sand or inert absorbent and remove to safe place.

Other information： Dispose of materials or solid residues at an authorized site.

6.4 Reference to other sections: See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

6.5 Additional information: Not applicable.

Section 7 Handling and storage

7.1 Precautions for safe handling:

7.1.1 Protective measures: Ensure good ventilation of the work station. Wear personal protective equipment.

7.1.2 Advice on general occupational hygiene: Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities: Material should be stored in a clean, dry environment at 2 to 30°C in original packaging and not exposed to ignition sources.

7.3 Specific end use(s): Use as per instructions for use.

Section 8 Exposure Controls/Personal Protection

8.1 Control parameters:

8.1.1 National occupational exposure and biological limit values：

ProClin™ 300 (55965-84-9)	
Austria - Occupational Exposure Limits	
MAK (OEL TWA)	0.05 mg/m³ (5-Chloro-2-methyl-2,3-dihydroisothiazol-3-one and 2-methyl-2,3-dihydroisothiazol-3-one mixture in ratio 3:1)
OEL chemical category	Skin sensitizer

8.1.2 Recommended monitoring procedures: No additional information available.

8.1.3 Air contaminants formed: No additional information available.

8.1.4 DNEL and PNEC-Values: No additional information available.

8.1.5. Control banding: No additional information available.

8.2 Exposure controls:

8.2.1Appropriate engineering controls: Ensure good ventilation of the work station.

8.2.2 Individual protection measures, such as personal protective equipment:

8.2.2.1 Eye/face protection

Eye protection: Safety glasses.

Face protection: No special protective equipment required.

8.2.2.2 Skin protection

Skin and body protection: Wear suitable protective clothing.

Hand protection: Protective gloves.

8.2.2.3 Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment.

8.2.2.4 Thermal hazards: No additional information available

8.2.2.1 Eye/face protection

Eye protection: Safety glasses.

Face protection: No special protective equipment required.

8.2.3 Environmental exposure controls: Avoid discharge into the environment. According to local regulations, Federal and official regulations.

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:	Liquid
Physical state:	Liquid
Colour:	Colorless
Odour:	Odorless
Odour threshold:	Not available
pH:	Not available
Melting point/range (°C):	Not available
Boiling point/range (°C):	Not available
Freezing point:	Not available
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (solid, gas):	Not available
Ignition temperature (°C):	Not available

Upper/lower flammability/explosive limits:	Not available
Vapour pressure:	Not available
Vapour pressure (50 °C) :	Not available
Vapour pressure (20°C):	Not available
Density:	Not available
Vapour density:	Not available
Relative Density:	Not available
Relative vapour density (20°C):	Not available
Bulk density (kg/m^3):	Not available
Water solubility (g/l):	Not available
n-Octanol/Water (log Po/w):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity, dynamic (mPa.s):	Not available
Solubility:	Not available
Partition coefficient n-octanol/water (Log Kow):	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
Molecular Formula:	Not available
Molecular Weight:	Not available
Particle size:	Not available
Particle size distribution :	Not available
Particle shape :	Not available
Particle aspect ratio :	Not available
Particle aggregation state :	Not available
Particle agglomeration state :	Not available
Particle specific surface area :	Not available
Particle dustiness :	Not available

9.2. Other information:

9.2.1. Information with regard to physical hazard classes:

Fat solubility(solvent– oil to be specified) etc:	Not available
Surface tension:	Not available
Dissociation constant in water(pKa):	Not available
Specific gravity:	Not available

9.2.2. Other safety characteristics

Oxidation-reduction Potential:	Not available

Section 10 Stability and reactivity

10.1 Reactivity: The substance is stable under normal storage and handling conditions.

10.2 Chemical stability: Stable at 2 to 30°C in closed containers under normal storage and handling conditions.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: None under recommended storage and handling conditions (see section 7)

10.5 Incompatible materials: Acids.

10.6 Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral): Not classified.

Acute toxicity (dermal): Not classified.

Acute toxicity (inhalation): Not classified.

ProClin™ 300 (55965-84-9)	
LD50 oral rat	LD50 oral rat
LD50 dermal rabbit	LD50 dermal rabbit

Skin corrosion/Irritation: Not classified

Serious eye damage/irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

STOT- single exposure: Not classified

STOT-repeated exposure: Not classified

Aspiration hazard: Not classified

11.2 Information on other hazards:

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties： The mixture does not contain substance(s) included in the list established in accordance with (EC) No. 1907/2006 for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2. Other information No additional information available.

Section 12 Ecological information

12.1 Toxicity:

Ecology – general：	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)：	Not classified
Hazardous to the aquatic environment, long-term (chronic)：	Not classified

12.2 Persistence and degradability: Not available.

12.3 Bioaccumulative potential:

Ethoxylated acetylenic diols (9014-85-1)	
Partition coefficient n-octanol/water (Log Pow)	(>1.8 - <2.5 - at 21 °C)

ProClin™ 300 (55965-84-9)	
BCF - Fish [1]	(54 dimensionless (whole body w.w.)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (at 20 °C (at pH >=5-<=9)

12.4 Mobility in soil: Not available.

12.5 Results of PBT&vPvB assessment: Not available.

Buffer of FOB One Step Fecal Occult Blood Test Device

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties：	The mixture does not contain substance(s) included in the list established in accordance with (EC) No. 1907/2006 for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

12.7. Other adverse effects: Not available.

Section 13 Disposal considerations

13.1 Waste treatment methods: Dispose of contents/container in accordance with licensed collector's sorting instructions.

13.2 Product / Packaging disposal: Dispose of contents/container in accordance with licensed collector's sorting instructions.

Section 14 Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				

Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport	Not regulated.
Transport by sea	Not regulated.
Air transport	Not regulated.
Inland waterway transport	Not regulated.
Rail transport	Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

Section 15 Regulation information

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

15.1.1. EU-Regulations

- Contains no REACH substances with Annex XVII restrictions
- Contains no substance on the REACH candidate list
- Contains no REACH Annex XIV substances
- Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.
- Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
- Contains no substance subject to (EC) No. 1907/2006 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

Section 16 Other information

16.1 Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate

BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

16.2 Data sources: ECHA (European Chemicals Agency). Loli.

16.3 Training advice: Normal use of this product shall imply use in accordance with the instructions on the packaging.

16.4 Full text of H- and EUH-statements:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Sens. 1A	Skin sensitisation, category 1A
Skin Sens. 1B	Skin sensitisation, category 1B

16.5 Indication of changes:

Version AF Amended by EU No 2020/878

16.6 Relevant R- phrases (number and full text):

Not applicable.

16.7 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

16.8 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

文件更改概要

Document Change Summary

审批单 编号 CO/DAF	更改概述 Summary of Changes
CO-10131403	因法规更新，将 Article 59(1) of REACH 更新为(EC) No. 1907/2006、Regulation (EU) 2019/1148 更新为(EC) No. 1907/2006。