

тм

AB-PINACA Pentanoic Acid Calibrator and Control Set

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 17/02/2022 Version: AB

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1. Product identifier		
Product form Product name Product code Product group Other means of identification	 Mixture AB-PINACA Pentanoic Acid Calibrator and Control Set 10030-5, 3012-5, 10030-5EX, 3012-5EX, 10030-5INT, 3012-5INT Trade product AB-PINACA Pentanoic Acid Calibrator (10 ng/mL), AB-PINACA Pentanoic Acid Low Control (5 ng/mL), AB-PINACA Pentanoic Acid High Control (15 ng/mL) 	
1.2. Relevant identified uses of the substan	nce or mixture and uses advised against	
 1.2.1. Relevant identified uses Use of the substance/mixture 1.2.2. Uses advised against No additional information available 	: For validity determination, and calibration of Immunalysis Enzyme Assays	
1.3. Details of the supplier of the safety dat	a sheet	
Immunalysis Corporation 829 Towne Center Drive 91767 Pomona, CA - USA T +1 (909)-482-0840 immunalysis.com		
Abbott Rapid Dx International Limited Parkmore East Business Park, Ballybrit, Co. Galway, H91 VK7E, Ireland <u>Abbott.SDS@abbott.com</u>		
1.4. Emergency telephone number		
Emergency number	 Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7days/week). -Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands. -Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea. 	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

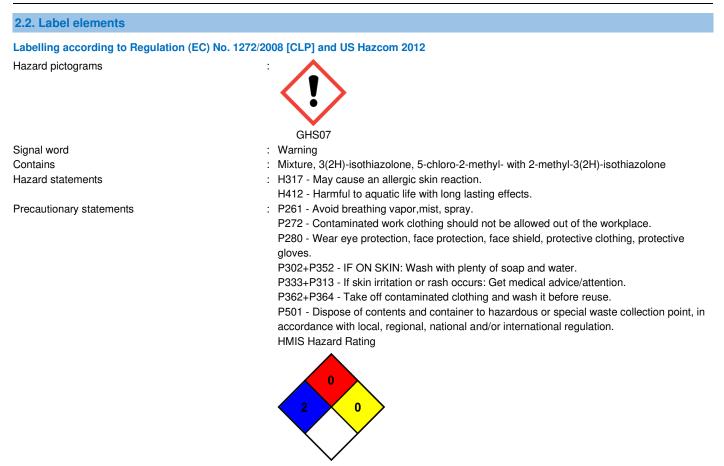
Classification according to Regulation (EC) No. 1272/2008 [CLP] and US Hazcom 2012

Skin sensitisation, Category 1A	H317
Hazardous to the aquatic environment — Chronic Hazard, Category 3	H412

Adverse physicochemical, human health and environmental effects

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations



2.3. Other hazards

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH 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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	0,003 %	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Specific concentration limits (EU)		
Name	Product identifier	Specific concentration limits (EU)
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	CAS-No.: 55965-84-9 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. 1B, H314

SECTION 4: First Aid measures

4.1. Description of first aid measures	
First-aid measures general	: If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.
First-aid measures after inhalation	: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.
First-aid measures after skin contact	: IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.
First-aid measures after eye contact	: IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing if pain, blinking, or irritation develops or persists, get medical attention. Continue rinsing.
First-aid measures after ingestion	: IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. Get medical attention if you feel unwell.
4.2. Most important symptoms and effect	ts, both acute and delayed
Symptoms/effects Symptoms/effects after inhalation Symptoms/effects after skin contact Symptoms/effects after eye contact Symptoms/effects after ingestion	 Not expected to present a significant hazard under anticipated conditions of normal use. May cause respiratory irritation. May cause an allergic skin reaction. Direct contact with eyes is likely to be irritating. May cause minor gastrointestinal irritation.

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

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media Unsuitable extinguishing media	 Dry powder. Foam. Water spray. Carbon dioxide (CO₂). None known.
5.2. Special hazards arising from the su	ubstance or mixture
Fire hazard Explosion hazard	Not flammable.Product is not explosive.
5.3. Advice for firefighters	
Firefighting instructions	: Use cold water spray to cool fire-exposed containers to minimize risk of rupture. Do not dispose of fire-fighting water in the environment. Dispose of in accordance with relevant local regulations. Prevent human exposure to fire, fumes, smoke and products of combustion.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 6: Accidental release measures		
6.1. Personal precautions, protective equipment and emergency procedures		
General measures	: Evacuate area. Keep upwind. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.	
6.1.1. For non-emergency personnel		
Protective equipment Emergency procedures	 Wear Protective equipment as described in Section 8. Evacuate unnecessary personnel. 	
6.1.2. For emergency responders		
Protective equipment	: For further information refer to section 8: "Exposure controls/personal protection".	
6.2. Environmental precautions		
Prevent entry to sewers and public waters. Avoid release to the environment. Notify authorities if product enters sewers or public waters.		
6.3. Methods and material for containment and cleaning up		

For containment Methods for cleaning up	 Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Prevent entry to sewers and public waters. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Sweep or shovel spills into appropriate container for disposal.
6.4. Reference to other sections	

No additional information available

SECTION 7: Handling and storage			
7.1. Precautions for safe handling			
Do not handle until all safety precautions have been read and understood. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Ensure good ventilation of the work station. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.			
7.2. Conditions for safe storage, including any incompatibilities			
Keep in properly labeled containers.			

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National occupational exposure and biological limit values

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)	
Austria - Occupational Exposure Limits	
MAK (OEL TWA)	0.05 mg/m ³
Germany - Occupational Exposure Limits (TRGS 900)	
AGW (OEL TWA) [1]	0.2 mg/m ³ inhalable fraction
AGW (OEL C) 0.4 mg/m ³ inhalable fraction	

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)		
Switzerland - Occupational Exposure Limits		
MAK (OEL TWA) [1]	0.2 mg/m ³ inhalable fraction	
KZGW (OEL STEL)	0.4 mg/m ³ inhalable fraction	
United States - Occupational Exposure Limits		
Remark (ACGIH)	OELs not established	
Remark (OSHA)	OELs not established	

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

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Protective goggles. Wear labcoat with full coverage clothing.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles. Eye protection should be classified under EN 167(EU)

8.2.2.2. Skin protection

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure. [EN 14605:2005 and EN 13034:2005]

Hand protection:

Use gloves appropriate to the work environment. Gloves should be classified under Standard EN 374 or ASTM F1296.

8.2.2.3. Respiratory protection

Respiratory protection:

Where vapour, mist, or dust exceed PELs or other applicable OELs, use the European Standard EN 529:2005 approved dust/particulate respiratory protective equipment.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 9: Physical and chemical properties 9.1. Information on basic physical and chemical properties Physical state : Liquid Colour : Yellow Odour : Odourless Odour threshold : Criteria for classification not met pН : 6,9 - 7,1 Relative evaporation rate (butylacetate=1) : Criteria for classification not met Melting point : Criteria for classification not met Freezing point : Criteria for classification not met

: Criteria for classification not met
: Criteria for classification not met
: 1 g/ml
: Criteria for classification not met

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

None under normal use.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No data available.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)

: Not classified

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Acute toxicity (dermal) Acute toxicity (inhalation)	: Not classified : Not classified	
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)		
LD50 oral rat	53 mg/kg	
Skin corrosion/irritation	: Not classified	
Serious eye damage/irritation	pH: 6,9 - 7,1 : Not classified pH: 6,9 - 7,1	
Respiratory or skin sensitisation	: May cause an allergic skin reaction.	
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	:	The mixture does not contain substance(s) included in the list established in accordance
disrupting properties		with Article 59(1) of REACH 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

SECTION 12: Ecological information		
12.1. Toxicity		
Hazardous to the aquatic environment, short-term : (acute)	No information available. Not classified Harmful to aquatic life with long lasting effects.	
12.2. Persistence and degradability		
AB-PINACA Pentanoic Acid Calibrator and Control Set		
Persistence and degradability	No data available.	
12.3. Bioaccumulative potential		
AB-PINACA Pentanoic Acid Calibrator and Control Set		
Bioaccumulative potential	No information available.	

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

12.6. 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 Article 59(1) of REACH 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

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations	S
13.1. Waste treatment methods	
Waste treatment methods	 Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without a permit.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

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

14.1. UN number	
UN-No. (ADR) UN-No. (IMDG) UN-No. (IATA) UN-No. (ADN) UN-No. (RID)	 Not applicable Not applicable Not applicable Not applicable Not applicable
14.2. UN proper shipping name	
Proper Shipping Name (ADR) Proper Shipping Name (IMDG) Proper Shipping Name (IATA) Proper Shipping Name (ADN) Proper Shipping Name (RID)	 Not applicable Not applicable Not applicable Not applicable Not applicable
14.3. Transport hazard class(es)	
ADR Transport hazard class(es) (ADR)	: Not applicable
IMDG Transport hazard class(es) (IMDG)	: Not applicable
IATA Transport hazard class(es) (IATA)	: Not applicable
ADN Transport hazard class(es) (ADN)	: Not applicable
RID Transport hazard class(es) (RID)	: Not applicable
14.4. Packing group	
Packing group (ADR) Packing group (IMDG)	: Not applicable : Not applicable

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Packing group (IATA) Packing group (ADN) Packing group (RID)	 Not applicable Not applicable Not applicable
14.5. Environmental hazards	
Dangerous for the environment Marine pollutant Other information	 No No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea (IMDG)

Not applicable

Air transport (IATA)

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory 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

This device is compliant with the requirements of EU regulation 2017/746 on In-vitro Diagnostic Devices (IVDR)

15.1.2. National regulations

Germany	
Water hazard class (WGK)	: WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)
WGK remark	: Classification based on the components in compliance withVerwaltungsvorschrift wassergefährdender Stoffe (VwVwS) of 17 May 1999
Hazardous Incident Ordinance (12. BImSchV)	: Is not subject of the Hazardous Incident Ordinance (12. BImSchV)
Netherlands	
SZW-lijst van kankerverwekkende stoffen	: None of the components are listed
SZW-lijst van mutagene stoffen	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	: None of the components are listed

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Denmark Danish National Regulations	: Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product
Switzerland Storage class (LK)	: LK 10/12 - Liquids

US Federal regulations

All chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb 2019, as amended Feb 2021 or are otherwise exempt, or regulated by other agencies such as FDA or FIFRA.

US State regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

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. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) 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	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1	Skin sensitisation, Category 1	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
H310	Fatal in contact with skin.	
H314	Causes severe skin burns and eye damage.	
H315	Causes skin irritation.	
H317	May cause an allergic skin reaction.	
H319	Causes serious eye irritation.	
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.	

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Abbreviations	Abbreviations and acronyms		
ACGIH	American Conference of Governement Industrial Hygienists		
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways		
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road		
CAS-No.	Chemical Abstract Service number		
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008		
DNEL	Derived-No Effect Level		
EC50	Median effective concentration		
EC-No.	European Community number		
ED	Endocrine disrupting properties		
EN	European Standard		
IATA	International Air Transport Association		
IMDG	International Maritime Dangerous Goods		
LD50	Median lethal dose		
OEL	Occupational Exposure Limit		
OSHA	Occupational Safety and Health Administration		
PBT	Persistent Bioaccumulative Toxic		
PNEC	Predicted No-Effect Concentration		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006		
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail		
SDS	Safety Data Sheet		
STOT	Specific target organ toxicity		
TRGS	Technical Rules for Hazardous Substances		
vPvB	Very Persistent and Very Bioaccumulative		
WGK	Water Hazard Class		

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Data sources : Classification for the USA in accordance with 29 CFR 1910.1200 (2012). Classification for the EU in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Classification for Turkey in accordance with the Classification, Labelling and Packaging of Substances and Mixtures (SEA) Regulation published in the Official Journal numbered 28848 on December 11, 2013. ECHA (European Chemicals Agency). Normal use of this product shall imply use in accordance with the instructions for use and Training advice : corresponding product packaging.

Indication of changes:

Revision AB: Updated SDS to align with Regulation (EC) No. 1272/2008 [CLP] and US Hazcom 2012.

Other information

: Author: Pace.

SDS Prepared for Immunalysis Corporation by: Pace Analytical Services, Inc. Product Regulatory Services Group

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1800 Elm Street Minneapolis, MN 55414 United States 612-656-1175 paceSDS@pacelabs.com

Classification according to Regulation (EC) No. 1272/2008	Classification procedure
Skin sensitisation, Category 1A	Specific concentration limit
Hazardous to the aquatic environment — Chronic Hazard, Category 3	Calculation method

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.