



Buprenorphine Urine 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: 16/12/2021 Version: AB

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Buprenorphine Urine Calibrator and Control Set
Product code : C336UR-10-1, C336UR-10-2, C336UR-10-5, 04W30-01, 04W30-02, 04W30-10, 04Z42-01, 04Z42-02, 04Z42-10, C336UR-10-1INT, C336UR-10-2INT, C336UR-10-5INT, 04W30-03, 04W30-04, 04W30-11, 04Z42-03, 04Z42-04, 04Z42-11
Product group : Trade product
Other means of identification : Buprenorphine Urine Calibrator (5 ng/mL), Buprenorphine Urine Calibrator (10 ng/mL), Buprenorphine Urine Calibrator (20 ng/mL), Buprenorphine Urine Calibrator (40 ng/mL), Buprenorphine Urine Low Control (3.75 ng/mL), Buprenorphine Urine High Control (6.25 ng/mL), Negative Reference Calibrator

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For validity determination, and calibration of Immunalysis HEIA™ Buprenorphine Assay

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data 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
Abbott.SDS@abbott.com

1.4. Emergency telephone number

Emergency number : Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/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
Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

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

Hazard pictograms



GHS07

Signal word

: Warning

Contains

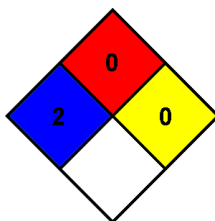
: Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone

Hazard statements

: H317 - May cause an allergic skin reaction.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements

: P261 - Avoid breathing vapor,mist, spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear eye protection, face protection, face shield, protective clothing, protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
HMIS Hazard Rating



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)

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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

Full text of H-statements: see section 16

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 effects, both acute and delayed

Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Direct contact with eyes is likely to be irritating.
Symptoms/effects after ingestion	: May cause minor gastrointestinal irritation.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry powder. Foam. Water spray. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: 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.

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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 : Wear Protective equipment as described in Section 8.
Emergency procedures : 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 : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Prevent entry to sewers and public waters.
Methods for cleaning up : 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

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

Storage conditions : 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

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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

No additional information available

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Solution
Colour	: Yellow
Odour	: Odourless
Odour threshold	: Criteria for classification not met
pH	: 6,90 - 7,10
Relative evaporation rate (butylacetate=1)	: Criteria for classification not met
Melting point	: Criteria for classification not met
Freezing point	: Criteria for classification not met
Boiling point	: Criteria for classification not met
Flash point	: Criteria for classification not met
Auto-ignition temperature	: Criteria for classification not met
Decomposition temperature	: Criteria for classification not met
Flammability (solid, gas)	: Criteria for classification not met
Vapour pressure	: Criteria for classification not met
Relative vapour density at 20 °C	: Criteria for classification not met
Relative density	: Criteria for classification not met
Density	: 1 g/ml
Solubility	: Criteria for classification not met
Partition coefficient n-octanol/water (Log Pow)	: Criteria for classification not met
Viscosity, kinematic	: Criteria for classification not met
Viscosity, dynamic	: Criteria for classification not met
Explosive properties	: Criteria for classification not met
Oxidising properties	: Criteria for classification not met
Explosive limits	: 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.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : 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 pH: 6,90 - 7,10
Serious eye damage/irritation	: Not classified pH: 6,90 - 7,10
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 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

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No information available.
Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

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Persistence and degradability	No data available.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	No information available.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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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

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) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : 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) : Not applicable
Packing group (IMDG) : Not applicable

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Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : 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 with Verwaltungsvorschrift 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

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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

California Proposition 65 - 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.

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Abbreviations and acronyms	
ACGIH	American Conference of Government 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

Data sources : Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
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).

Training advice : Normal use of this product shall imply use in accordance with the instructions for use and corresponding product packaging.

Indication of changes:

Revision AA: New SDS Created.

Revision AB: Update to Section 1, 9.1, 10, 16. Added translation language: Czech.

Other information : Author: Pace.

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

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Product Regulatory Services Group
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Minneapolis, MN 55414
United States
612-656-1175
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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.