cTHC 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: 17/02/2022 Version: AC

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

1.1. Product identifier

Product form : Mixture
Product name : cTHC Urine Calibrator and Control Set
Product code : 10011-5, 10011-15, 10011-25, 10012-5, 10012-15, 10012-25, 10013-5, 10013-15, 10013-25, 10014-5, 10014-15, 10014-25, 3005-5, 3005-15, 3005-25, 10011-15INT, 10011-25INT, 10012-15INT, 10012-25INT, 10013-15INT, 10013-25INT, 10014-15INT, 10014-25INT, 3005-5INT, 3005-15INT, 3005-25INT
Product group : Trade product
Other means of identification : cTHC Urine Calibrator (20 ng/mL), cTHC Urine Calibrator (50 ng/mL), cTHC Urine Calibrator (100 ng/mL), cTHC Urine Calibrator (200 ng/mL), cTHC Urine Low Control (37.5 ng/mL), cTHC Urine High Control (62.5 ng/mL)

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 Enzyme Assays

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, 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

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

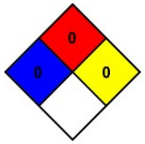
Labelling according to Regulation (EC) No. 1272/2008 [CLP] and US Hazcom 2012

No labelling applicable
HMIS/NFPA Rating:

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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]
Contains no hazardous ingredients at levels requiring disclosure by OSHA Hazard Communication Standard (29 CFR 1910.1200) or Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878			

SECTION 4: First Aid measures

4.1. Description of first aid measures

First-aid measures general : 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 comfortable position for breathing.

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.

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.

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 minor respiratory irritation.

Symptoms/effects after skin contact : May cause minor skin irritation.

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. Carbon dioxide (CO_2).

5.2. Special hazards arising from the substance or mixture

Fire hazard : Criteria for classification not met
Explosion hazard : Criteria for classification not met

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

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.
Methods for cleaning up : Keep in suitable, closed containers for disposal. Avoid dust formation.

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 : Use only with adequate ventilation. Do not breathe vapours, mist. Keep container tightly closed in a cool place. Wash thoroughly after handling. Avoid contact with skin, eyes and clothing.

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

Sodium chloride (7647-14-5)	
Latvia - Occupational Exposure Limits	
OEL TWA	5 mg/m³

Sodium chloride (7647-14-5)	
USA - 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.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:
Use eye protection suitable to the environment. Avoid direct contact with eyes. 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	:	6,9 - 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
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
Skin corrosion/irritation	:	Not classified pH: 6,9 - 7,1
Serious eye damage/irritation	:	Not classified pH: 6,9 - 7,1
Respiratory or skin sensitisation	:	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 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)	:	Not classified

12.2. Persistence and degradability

cTHC Urine Calibrator and Control Set	
Persistence and degradability	No information available.

12.3. Bioaccumulative potential

cTHC Urine Calibrator and Control Set	
Bioaccumulative potential	No information available.

12.4. Mobility in soil

cTHC Urine Calibrator and Control Set	
Ecology - soil	No information available.

12.5. Results of PBT and vPvB assessment

No additional information available

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

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 nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)
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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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

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

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

Other information : Author: Pace.

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Classification according to Regulation (EC) No. 1272/2008	Classification procedure
Not hazardous	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.