Safety Data Sheet

acc. to Regulation (EC) No. 1907/2006 (REACH)

GENERIC EU SDS - NO COUNTRY SPECIFIC DATA

STAT-IntraOperative-Intact PTH Immunoassay Kit

Version number: 10.0
Replaces version of: 01.07.2019 (9)

Revision: 27.09.2023

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

1.1 Product identifier

Trade name	**STAT-IntraOperative-Intact PTH Immunoassay Kit**
Registration number (REACH)	not relevant (mixture)
Unique formula identifier (UFI)	H200-U0CW-500Y-QNAK
Alternative name(s)	STAT-IntraOperative-Intact PTH Immunoassay Kit
Article number	4K-IPT-00

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

Relevant identified uses	For in vitro diagnostic use only (IVD) Professional use
Uses advised against	Do not use for squirting or spraying Do not use for products which come into direct contact with the skin

1.3 Details of the supplier of the safety data sheet

Future Diagnostics
Nieuweweg 279
6603 BN Wijchen
Netherlands

Telephone: +31 (0) 24 6452900
Telefax: +31 (0) 24 6452899
e-mail: info@future-diagnostics.nl
Website: www.future-diagnostics.com

e-mail (competent person)	info@future-diagnostics.nl

1.4 Emergency telephone number

Emergency information service	+31 (0)88 024 5700 24 hours emergency information

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard state-ment
2.16	substance or mixture corrosive to metals	1	Met. Corr. 1	H290
3.2	skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	serious eye damage/eye irritation	1	Eye Dam. 1	H318

For full text of H-phrases: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis.

2.2 Label elements

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

- signal word Danger

- pictograms

GHS05

- hazard statements

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.

- precautionary statements

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P390	Absorb spillage to prevent material damage.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

- hazardous ingredients for labelling

Contains: sodium hydroxide.

2.3 Other hazards

There is no additional information.

Results of PBT and vPvB assessment

Does not contain any substances that are assessed to be PBT or vPvB ≥ 0.1%.

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0.1%.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture).

3.2 Mixtures

The product does not contain (other) ingredients which are classified according to present knowledge of the supplier and contribute to the classification of the product and hence require reporting in this section.
REACH information: In order to use the most updated information we have incorporated data available via the public REACH dossier into the safety datasheet. Ingredients in the mixture do not fulfill the tonnage requirements for REACH registration as they are produced and/or imported <1 tonne per year.

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
sodium hydroxide	CAS No 1310-73-2 EC No 215-185-5 REACH Reg. No 01-2119457892-27-xxxx	4	Met. Corr. 1 / H290 Skin Corr. 1A / H314 Eye Dam. 1 / H318		GHS-HC

Notes
GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

Name of sub-stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
sodium hydroxide	CAS No 1310-73-2	Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Dam. 1; H318: C ≥ 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %	-	-	

Remarks

All the percentages given are percentages by weight unless stated otherwise. For full text of H-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. In case of unconsciousness place person in the recovery position. Never give anything by mouth. Do not take off clothes. In all cases of doubt, or when symptoms persist, seek medical advice.

Following inhalation

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Immediately call a POISON CENTER/doctor. In case of respiratory tract irritation, consult a physician.

Following skin contact

Rinse immediately contaminated clothing and skin with plenty of water before removing clothes, if possible. Immediately call a POISON CENTER/doctor.

Following eye contact

Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Immediately call a POISON CENTER/doctor. Call a POISON CENTER or doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

For specialist advice physicians should contact the poison centre.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray; Alcohol resistant foam; Dry extinguishing powder; Carbon dioxide (CO2);
Co-ordinate firefighting measures to the fire surroundings.

Unsuitable extinguishing media

Water jet.

5.2 Special hazards arising from the substance or mixture

Substance or mixture corrosive to metals.

Hazardous combustion products

During fire hazardous fumes/smoke could be produced: sodium oxide.

5.3 Advice for firefighters

Keep containers cool with water spray. In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Self-contained breathing apparatus (SCBA). Standard protective clothing for firefighters.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

- specific notes/details

Do not pipette by mouth.

- handling of incompatible substances or mixtures

Do not mix with acids.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- corrosive conditions

Store in corrosive resistant container with a resistant inner liner.

- flammability hazards

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge.

- incompatible substances or mixtures

Keep away from alkalis, oxidising substances, acids.

Control of effects

Protect against external exposure, such as

High temperatures. UV-radiation/sunlight.

Consideration of other advice

Store unopened in the original packaging in a dry and well-ventilated place.

- specific designs for storage rooms or vessels
- storage temperature

Recommended storage temperature: 15 – 30 °C

- packaging compatibilities

Keep only in original container.

7.3 Specific end use(s)

There is no additional information.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

No information available.

Relevant DNELs/DMELs/PNECs and other threshold levels

Relevant DNELs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
sodium hydroxide	1310-73-2	DNEL	1 mg/m³	human, inhalatory	worker (industry)	chronic - local effects
sodium hydroxide	1310-73-2	DNEL	1 mg/m³	human, inhalatory	consumer (private households)	chronic - local effects

8.2 Exposure controls

Appropriate engineering controls

General ventilation. Provide eyewash stations and safety showers at the workplace.

Individual protection measures (personal protective equipment)

Eye/face protection

Use safety goggle with side protection (EN 166).

Skin protection

Chemical protective clothing. Protective clothing (EN 340 & EN ISO 13688).

- hand protection

Wear suitable gloves. Check leak-tightness/impermeability prior to use. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Chemical protection gloves are suitable, which are tested according to EN 374. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- type of material

Nitrile rubber

- material thickness

Use gloves with a minimum material thickness: ≥ 0,11 mm.

- breakthrough time of the glove material

Use gloves with a minimum breakthrough time of the glove material: >480 minutes (permeation: level 6).

- other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Type: B (against inorganic gases and vapours, colour code: Grey).

Environmental exposure controls

Take appropriate precautions to avoid uncontrolled release into the environment. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	odourless
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	non-combustible
Lower and upper explosion limit	LEL: UEL: not determined
Flash point	not applicable
Auto-ignition temperature	not relevant
Decomposition temperature	no data available
pH (value)	>12 (base)
Kinematic viscosity	not determined

Solubility

Water solubility	miscible in any proportion

Partition coefficient n-octanol/water (log value)	this information is not available

Vapour pressure	not determined

Density and/or relative density

Density	not determined
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)

9.2 Other information

There is no additional information.

Information with regard to physical hazard classes	there is no additional information

Other safety characteristics

Miscibility	Completely miscible with water.

SECTION 10: Stability and reactivity

10.1 Reactivity

Substance or mixture corrosive to metals.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Strong acids and bases, strong oxidisers, metals, light metals (e.g. aluminium and magnesium), ammonia (NH3).

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

Acids, zinc, metals, light metals (e.g. aluminium and magnesium), lead, releases hydrogen by reaction with metals

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification acc. to GHS

Acute toxicity

Shall not be classified as acutely toxic.

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Other information

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

11.2 Information on other hazards

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0.1%.

Other information

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
sodium hydroxide	1310-73-2	LC50	<180 $^{mg}/_{l}$	fish	96 h
sodium hydroxide	1310-73-2	EC50	40,4 $^{mg}/_{l}$	aquatic invertebrates	48 h

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
sodium hydroxide	1310-73-2	EC50	22 $^{mg}/_{l}$	microorganisms	15 min
sodium hydroxide	1310-73-2	growth (EbCx) 10%	161 $^{mg}/_{l}$	microorganisms	2 min

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Does not contain any substances that are assessed to be PBT or vPvB ≥ 0.1%.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0.1%.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment.

Waste treatment of containers/packagings

Only packagings which are approved (e.g. acc. to the Dangerous Goods Regulations) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1 UN number or ID number

UN RTDG	UN 1824
IMDG-Code	UN 1824
ICAO-TI	UN 1824

14.2 UN proper shipping name

UN RTDG	SODIUM HYDROXIDE SOLUTION
IMDG-Code	SODIUM HYDROXIDE SOLUTION
ICAO-TI	Sodium hydroxide solution

14.3 Transport hazard class(es)

UN RTDG	8
IMDG-Code	8
ICAO-TI	8

14.4 Packing group

UN RTDG	II
IMDG-Code	II
ICAO-TI	II

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

No data available.

Information for each of the UN Model Regulations

Transport information - national regulations - additional information (UN RTDG)

UN number	1824
Class	8
Packing group	II
Danger label(s)	8

Special provisions (SP)	- (UN RTDG)
Excepted quantities (EQ)	E2 (UN RTDG)
Limited quantities (LQ)	1 L (UN RTDG)

International Maritime Dangerous Goods Code (IMDG) - additional information

Marine pollutant	-
Danger label(s)	8

Special provisions (SP)	-
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
EmS	F-A, S-B
Stowage category	A
Segregation group	18 - Alkalis

International Civil Aviation Organization (ICAO-IATA/DGR) - additional information

Danger label(s)	8

Special provisions (SP)	A3
Excepted quantities (EQ)	E2
Limited quantities (LQ)	0,5 L

SECTION 15: Regulatory information

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

This Safety Data Sheet is purely informative and does comply with EU regulations, but not with country-specific regulations.

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	Restriction	No
STAT-IntraOperative-Intact PTH Immunoassay Kit	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	R3	3
sodium hydroxide	substances in tattoo inks and permanent make-up	R75	75

Legend

R3 1. Shall not be used in:
- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ash-trays,
- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
2. Articles not complying with paragraph 1 shall not be placed on the market.
3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
— can be used as fuel in decorative oil lamps for supply to the general public, and
— present an aspiration hazard and are labelled with H304.
4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
(a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: “Keep lamps filled with this liquid out of the reach of children”; and, by 1 December 2010, “Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage”;
(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: ‘Just a sip of grill lighter fluid may lead to life threatening lung damage’;
(c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not

Legend

exceeding 1 litre by 1 December 2010.';

Legend

R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
(i) 0,1 % by weight, if the substance is used solely as a pH regulator;
(ii) 0,01 % by weight, in all other cases;
(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
(i) “Rinse-off products”;
(ii) “Not to be used in products applied on mucous membranes”;
(iii) “Not to be used in eye products”;
(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture “for tattooing purposes” means injection or introduction of the mixture into a person’s skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
(a) the statement “Mixture for use in tattoos or permanent make-up”;
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. “Ingredient” means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement “pH regulator” for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.
The information shall be clearly visible, easily legible and marked in a way that is indelible.
The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.
Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.
Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.
8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes.
9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).
10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning.

Legend

Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

None of the ingredients are listed.

Seveso Directive

2012/18/EU (Seveso III)

No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

None of the ingredients are listed.

Water Framework Directive (WFD)

List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
sodium hydroxide	Metals and their compounds		a)	

Legend
A) Indicative list of the main pollutants

Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

None of the ingredients are listed.

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Complete revision of the safety data sheet.

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level

Abbr.	Descriptions of used abbreviations
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LEL	Lower explosion limit (LEL)
Met. Corr.	Substance or mixture corrosive to metals
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
SVHC	Substance of Very High Concern
UEL	Upper explosion limit (UEL)
UN RTDG	UN Recommendations on the Transport of Dangerous Good
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

UN Recommendations on the Transport of Dangerous Good. International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.
Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

STAT-IntraOperative-Intact PTH Immunoassay Kit

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.

Disclaimer

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