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

1.1 Product identifier

Trade name: DIN 53160 Saliva · two-part kit. Product number: SA1-KIT. Mixture; no REACH registration number, the mixture is not a registrable substance.

1.2 Relevant identified uses and uses advised against

Identified use: laboratory test reagent, for conformity and development testing to DIN 53160:2023-07. Professional use in a laboratory only.
Uses advised against: any use in or on humans or animals; any clinical, diagnostic or therapeutic use; use as a cosmetic, a medical device, a food or a feed; supply to the general public.

1.3 Details of the supplier of the safety data sheet

Synelys Biotech SAS
registered office to be added, Toulouse, France
hello@synelysbiotech.com

1.4 Emergency telephone number

Company: telephone to be added (office hours).
France, 24/7: ORFILA +33 (0)1 45 42 59 59, index of the national poison centres.
Germany, 24/7: Giftinformationszentrum, regional numbers at bvl.bund.de.
Within the EU: 112.

SECTION 2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP): the mixture is not classified. No physical, health or environmental hazard class is met.

2.2 Label elements

No hazard pictogram, no signal word and no hazard statement are required. Precautionary statements: none required. The label carries the product name, the reference standard, the batch number, the volume, the filling date, the best-before date and the statement that the product is for laboratory testing use only.

2.3 Other hazards

The mixture does not meet the PBT or vPvB criteria of Annex XIII and contains no constituent identified as having endocrine disrupting properties under Regulation (EU) 2018/1881. Spillage makes a floor slippery. A container held below its recommended temperature may freeze and split.

SECTION 3 Composition / information on ingredients

3.2 Mixtures

Aqueous mixture. Chemical characterisation: inorganic salts and organic metabolites in purified water.
Composition as formulated, per litre of ready-to-use solution:
Part A, Water (CAS 7732-18-5) > 99 % with magnesium, calcium, sodium and potassium chlorides. Part B, water with dipotassium hydrogen phosphate trihydrate (CAS 16788-57-1) and potassium carbonate (CAS 584-08-7). Each salt below 0.2 % in the reconstituted fluid.
No constituent is present at or above its generic concentration limit, so the mixture stays unclassified. Water is stated for completeness. No component is an SVHC of the candidate list at or above 0.1 % w/w.

SECTION 4 First aid measures

4.1 Description of first aid measures

General: remove soiled clothing. Show this safety data sheet to the doctor.
After inhalation: not an anticipated route of exposure, the product is a non-volatile aqueous solution. Move to fresh air if an aerosol has been generated.
After skin contact: wash with water and soap. If irritation persists, seek medical advice.
After eye contact: rinse with running water for at least 15 minutes, holding the eyelids apart. Remove contact lenses if present and easy to do. If irritation persists, seek medical advice.
After swallowing: rinse the mouth and drink water. Do not induce vomiting. Seek medical advice if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

None expected under the conditions of use. A prolonged skin contact with an acidic formulation may cause transient reddening. No delayed effect is known.

4.3 **Indication of any immediate medical attention and special treatment needed**	Symptomatic treatment. No specific antidote is known or required.

SECTION 5 Firefighting measures

5.1 **Extinguishing media**	Suitable: water spray, carbon dioxide, dry powder, alcohol resistant foam. The product itself is not combustible and does not sustain a fire. Unsuitable: none. Choose the media appropriate to the surrounding fire.
5.2 **Special hazards arising from the substance or mixture**	None specific. In a fire, evaporation of the water fraction may concentrate the dissolved salts and organic constituents in the residue. Thermal decomposition of the organic fraction can release carbon oxides and, where nitrogen bearing constituents are present, nitrogen oxides and ammonia.
5.3 **Advice for firefighters**	As in any fire, wear self-contained breathing apparatus and full protective clothing. Do not allow firefighting water to enter drains or watercourses.

SECTION 6 Accidental release measures

6.1 **Personal precautions, protective equipment and emergency procedures**	Wear the protective equipment of section 8. Beware of a slippery floor. No evacuation or special respiratory protection is required for a laboratory scale spill.
6.2 **Environmental precautions**	Do not discharge a bulk quantity to a drain, to surface water or to the ground. A laboratory quantity may be flushed with plenty of water where local regulations allow it.
6.3 **Methods and material for containment and cleaning up**	Contain with an inert absorbent (paper, sand, diatomite, universal binder). Collect into a labelled container and dispose of according to section 13. Rinse the area with water and dry it.
6.4 **Reference to other sections**	Safe handling: section 7. Personal protective equipment: section 8. Disposal: section 13.

SECTION 7 Handling and storage

7.1 **Precautions for safe handling**	Normal laboratory practice. Avoid contact with the eyes. Do not eat, drink or smoke where the product is handled. Wash the hands after handling. Close the container after use: an opened container is exposed to microbial contamination, and this product carries no preservative.
7.2 **Conditions for safe storage, including any incompatibilities**	Storage: room temperature, in the dark Shelf life: made to order, use-by date on the label · stability study of the two parts not yet run Container: two amber HDPE bottles (PP cap), mixed on use Keep away from direct sunlight and from freezing. Do not store with strong oxidisers or strong acids. Do not return an unused portion to the original container.
7.3 **Specific end use(s)**	Laboratory test reagent. See section 1.2. No exposure scenario is attached: a chemical safety assessment is not required for this mixture.

SECTION 8 Exposure controls / personal protection

8.1 **Control parameters**	No constituent is present in a quantity that requires an occupational exposure limit to be monitored at the workplace. No DNEL or PNEC is available for the mixture; none is required, no chemical safety assessment being called for.
8.2 **Exposure controls**	Engineering controls: general laboratory ventilation. A fume hood is not required. An eye wash station must be accessible. Eye and face protection: safety glasses to EN 166. Skin protection: nitrile gloves to EN ISO 374-1, minimum thickness 0.11 mm. Breakthrough time is not determined for this mixture and must be confirmed by the glove manufacturer. Laboratory coat. Respiratory protection: not required. Environmental exposure controls: see sections 6.2 and 13.

SECTION 9 Physical and chemical properties

9.1 **Information on basic physical and chemical properties**	Physical state: Kit. Liquid parts, supplied in separate containers and mixed on use. Colour: Colourless Odour: Odourless Melting point / freezing point: Approximately 0 °C, the mixture being predominantly water. Not determined experimentally. Boiling point or initial boiling point and boiling range: Approximately 100 °C at 1013 hPa. Not determined experimentally. Flammability: Non-flammable. Aqueous solution with no flammable constituent. Lower and upper explosion limit: Not applicable. Flash point: Not applicable. Auto-ignition temperature: Not applicable. Decomposition temperature: Not determined. pH: 6.8 ± 0.1 Kinematic viscosity: Not determined. Comparable to water. Solubility: Fully miscible with water. Not determined in organic solvents. Partition coefficient n-octanol/water (log value): Not determined. Not meaningful for a mixture of inorganic salts in water. Vapour pressure: Approximately 23 hPa at 20 °C, that of water. Not determined experimentally. Density and/or relative density: Approximately 1.00 to 1.02 g/cm³ at 20 °C. Not determined experimentally. Relative vapour density: Not determined. Particle characteristics: Not applicable.
9.2 **Other information**	No physical hazard class is met: the mixture is neither an oxidiser, nor a self-reactive, pyrophoric, self-heating or water-reactive mixture, nor corrosive to metals. No further safety characteristic is relevant.

SECTION 10 Stability and reactivity

10.1 **Reactivity**	No reactivity hazard under the recommended conditions of use and storage.
10.2 **Chemical stability**	Stable within the storage conditions of section 7.2 and up to the stated best-before date. Beyond it the fluid may drift outside the specification without any hazard arising.
10.3 **Possibility of hazardous reactions**	None known.
10.4 **Conditions to avoid**	Freezing, prolonged heating, direct sunlight, and an open container.
10.5 **Incompatible materials**	Strong oxidisers. Strong acids and bases. A chloride bearing fluid attacks unprotected carbon steel and some stainless grades: use inert labware.
10.6 **Hazardous decomposition products**	None under normal conditions. On thermal decomposition, see section 5.2.

SECTION 11 Toxicological information

11.1 **Information on hazard classes as defined in Regulation (EC) No 1272/2008**	No toxicological study has been performed on the mixture. The assessment below is derived from the constituents by the calculation method of Regulation (EC) No 1272/2008. It is not a statement that the mixture has been tested. Acute toxicity: Not classified. Skin corrosion/irritation: Not classified. Serious eye damage/eye irritation: Not classified. 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**	Endocrine disrupting properties: no constituent is identified as an endocrine disruptor under Regulation (EU) 2018/1881. Other information: the product is not intended for human or animal use. An acidic formulation may transiently redden the skin on prolonged contact.

SECTION 12 Ecological information

12.1 **Toxicity**	No data available on the mixture. No constituent is classified as hazardous to the aquatic environment.
12.2 **Persistence and degradability**	The organic fraction (urea, lactic acid, amino acids, glucose) is readily biodegradable. The inorganic salts are not degradable and dissociate in water. No test has been run on the mixture.
12.3 **Bioaccumulative potential**	Not expected. The constituents are water soluble and of low molecular mass.
12.4 **Mobility in soil**	High. A water soluble mixture spreads with soil water.
12.5 **Results of PBT and vPvB assessment**	The mixture does not meet the criteria of Annex XIII. PBT: no. vPvB: no.
12.6 **Endocrine disrupting properties**	No constituent is identified as an endocrine disruptor.
12.7 **Other adverse effects**	A large discharge raises the salinity and the nutrient load of a receiving water. Do not discharge in bulk.

SECTION 13 Disposal considerations

13.1 **Waste treatment methods**	Product: the waste is not classified as hazardous. A laboratory quantity may go to the drain with plenty of water where local rules allow it. A bulk quantity goes to a licensed waste contractor. A batch that has been in contact with a test specimen may carry released metals and is then handled as the specimen requires, not as this sheet describes. Waste code: assigned by the waste holder according to the origin of the waste, under Commission Decision 2000/532/EC. We do not assign it, not being the holder. Packaging: rinse the HDPE or PP container with water; it is then recyclable with the plastics stream.

SECTION 14 Transport information

14.1 **UN number or ID number**	Not applicable.
14.2 **UN proper shipping name**	Not applicable.
14.3 **Transport hazard class(es)**	Not applicable.

14.4 **Packing group**	Not applicable.
14.5 **Environmental hazards**	No. Not a marine pollutant.
14.6 **Special precautions for user**	None. Carry upright and secured. Protect from frost in winter transport.
14.7 **Maritime transport in bulk according to IMO instruments**	Not applicable.
	Not classified as dangerous goods under ADR, RID, ADN, IMDG or IATA. No dangerous goods declaration, no limited quantity marking and no dangerous-goods surcharge apply.

SECTION 15 Regulatory information

15.1 **Safety, health and environmental regulations specific for the substance or mixture**	Regulation (EC) No 1907/2006 (REACH): no constituent is on the Annex XIV authorisation list, and none is restricted under Annex XVII for this use. No constituent appears on the candidate list of substances of very high concern at or above 0.1 % w/w. Regulation (EC) No 1272/2008 (CLP): mixture not classified. Directive 2012/18/EU (Seveso III): not covered. Regulation (EU) 2019/1148 (explosives precursors): no listed substance. Regulation (EC) No 273/2004 (drug precursors): no listed substance. National provisions: none specific. The product is not a cosmetic, a medical device, a biocide, a detergent, a food or a feed, and none of those regimes applies to it.
15.2 **Chemical safety assessment**	No chemical safety assessment has been carried out for this mixture. None is required: the supplier of a mixture is not obliged to carry one out under Title II of Regulation (EC) No 1907/2006.

SECTION 16 Other information

Abbreviations	ADR/RID/ADN/IMDG/IATA: transport of dangerous goods by road, rail, inland waterway, sea and air. CLP: Regulation (EC) No 1272/2008. DNEL: derived no-effect level. PNEC: predicted no-effect concentration. PBT: persistent, bioaccumulative and toxic. vPvB: very persistent and very bioaccumulative. STOT: specific target organ toxicity. SVHC: substance of very high concern. CAS: Chemical Abstracts Service.
Full text of the hazard statements used	None. No hazard statement applies to this mixture.
Revision	Revision 3.0 of 2026-09-06. This revision rewrites the sheet per product: sections 1, 2, 3, 7, 9, 11 and 16 now carry values specific to this reference rather than to the range. Section 9 is completed to the list of Annex II as amended by Regulation (EU) 2020/878, and section 11 states derived classification rather than an untested conclusion. Supersedes all earlier editions.
Notice	The information above rests on the state of our knowledge on the date of issue. It describes the product with regard to safety requirements and is not a warranty of any property. The user remains responsible for observing the law applicable to their own use, and for the risk assessment of the workplace where the product is handled. This product is for laboratory testing use only, not for use in or on humans or animals.