SAFETY DATA SHEET

C.f.a.s. PAC

Version	Revision Date:	Date of last issue: 10-08-2021
1.10	03-15-2022	Date of first issue: 11-07-2015

SECTION 1. IDENTIFICATION

Product name : C.f.a.s. PAC

Product code : 03555941190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone
In case of emergencies : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section GHS Label elements contains the resulting labelling for the kit

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

CAL-FAS-LIPID F-mSw Cal 1

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	>= 30 - < 50
Sodium azide (Na(N3))	26628-22-8	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during fire fighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Avoid dust formation.

Environmental precautions	:	Prevent product from entering drains. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Provide appropriate exhaust ventilation at places where dust is formed.
Advice on safe handling	:	For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.
Conditions for safe storage	:	Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Materials to avoid	:	No materials to be especially mentioned.
Further information on storage stability	:	No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

CAL-FAS-LIPID F-mSw Cal 1

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust	5 mg/m3	OSHA P0

		fraction)		
Sodium azide (Na(N3))	26628-22-8	C	0.1 ppm (HN3)	NIOSH REL
		C (Vapor)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.3 mg/m3 (Sodium azide)	NIOSH REL
		C	0.1 ppm (Ammonia)	OSHA P0
		C	0.3 mg/m3 (Sodium azide)	OSHA P0
		C	0.29 mg/m3 (Sodium azide)	ACGIH

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

CAL-FAS-LIPID F-mSw Cal 1

Appearance : solid

Color : light yellow

Odor : odorless

Odor Threshold : Not applicable

pH	:	8.0 (77 °F / 25 °C) (as aqueous solution)
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use. Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid	:	Heat, flames and sparks. Direct sources of heat.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

CAL-FAS-LIPID F-mSw Cal 1

Acute toxicity

Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Acute oral toxicity	:	LD50 Oral (Rat): 29,700 mg/kg LD50 Oral (Mouse): 14,000 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: > 30 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Expert judgment

Sodium azide (Na(N3)):

Acute oral toxicity	:	LD50 Oral (Rat): 27 mg/kg
Acute inhalation toxicity	:	LC50: 0.053 - 0.52 mg/l Test atmosphere: dust/mist Target Organs: Respiratory system Acute toxicity estimate: > 0.05 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	:	LD50 Dermal (Rabbit): 20 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Method	:	OECD Test Guideline 439
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Species	:	Bovine cornea
Result	:	No eye irritation
Exposure time	:	4 h
Method	:	OECD Test Guideline 437

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Test Type	:	Local lymph node assay (LLNA)
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	negative
Assessment	:	Fatal if inhaled.

Germ cell mutagenicity

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: negative Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: negative Test Type: unscheduled DNA synthesis assay Test system: Chinese hamster lung cells Result: negative

Carcinogenicity

Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Remarks	:	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Sodium azide (Na(N3)):

Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Sodium azide (Na(N3)):

Species	:	Rat
NOAEL	:	5 mg/kg
LOAEL	:	10 mg/kg
Application Route	:	Oral
Exposure time	:	24 Months
Method	:	OECD Test Guideline 453

Species	:	Rat
NOAEL	:	10 mg/kg
LOAEL	:	20 mg/kg
Application Route	:	Oral
Exposure time	:	90 d

Repeated dose toxicity - : Fatal if inhaled.

Assessment

Aspiration toxicity

Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

No data available

Further information

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Remarks : Health injuries are not known or expected under normal use.

SECTION 12. ECOLOGICAL INFORMATION

CAL-FAS-LIPID F-mSw Cal 1

Ecotoxicity

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 h

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Sodium azide (Na(N3)):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 5.46 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 2.84 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.4 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.35 mg/l Exposure time: 96 h Test Type: static test Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 (Tetrahymena pyriformis): 5.6 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity	:	Very toxic to aquatic life.
Chronic aquatic toxicity	:	Very toxic to aquatic life with long lasting effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.

Persistence and degradability

Components:

Sodium azide (Na(N3)):

Biodegradability	:	Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulative potential

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Partition coefficient: n-octanol/water	:	log Pow: -3.67

Sodium azide (Na(N3)):

Partition coefficient: n-octanol/water	:	Remarks: Not applicable

Mobility in soil

No data available

Other adverse effects

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration). The product should not be allowed to enter drains, water courses or the soil. Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste

handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CAL-FAS-LIPID F-mSw Cal 1

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1
Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1
Sodium chloride (NaCl)	7647-14-5
Sodium azide (Na(N3))	26628-22-8

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1

The ingredients of this product are reported in the following inventories:

AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, lyophilized
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI : Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

CAL-FAS-LIPID F-mSw Cal 1

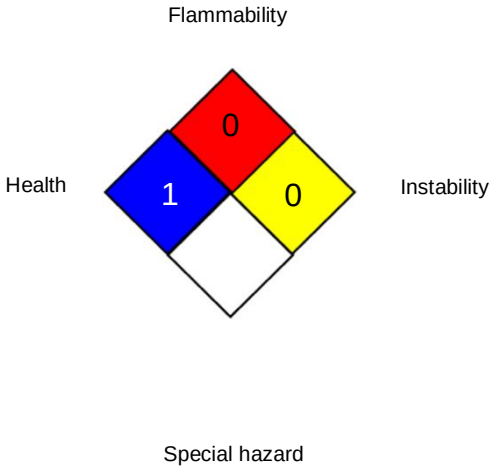
GHS label elements

Not a hazardous substance or mixture.

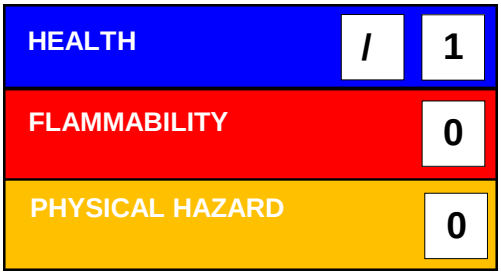
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC

- International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 03-15-2022

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2104