Section 1 - Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: **QS-21 VacciGrade™**

Catalog code: vac-qs21-1, vac-qs21-5, vac-qs21-25

CAS number: Not available

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

Identified use: Laboratory research. Only for professional use.

Uses advised against: Not for diagnostic, therapeutic, or household use.

1.3 Details of the supplier of the safety data sheet

Supplier:

InvivoGen US, 10515 Vista Sorrento Parkway
San Diego, California 92121, USA
(+1) 888 457 5873

InvivoGen Europe, 5 rue Jean Rodier
31400 Toulouse, France
+33 (0) 5 62 71 69 39

InvivoGen Asia, Unit 307, 3F,
8W Phase 2 Hong Kong Science Park,
Pak Shek Kok, Hong Kong
+852 3622 3480

Manufacturer:

SaponiQx, 3 Forbes Road, Lexington,
MA 02421-7305, USA
(+1) 781 674 4400

1.4 Emergency telephone number: ORFILA (INRS): +33 (0)1 45 42 59 59

Section 2 – Hazards identification

2.1 Classification of substance or mixture according to Regulation (EC) No 1272/2008 [EU-GHS/CLP] and GHS

Eye irritation (Category 2), H319
Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335

2.2 Label elements according to Regulation (EC) No 1272/2008 [CLP] and GHS

Pictogram

Signal word: Warning

Hazard statement(s)

H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Precautionary statement(s)
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/attention.

2.3 Other hazards
Endocrine Disruptor
To our knowledge, the substance or mixture does not contain any substances >0.1% that are included in the list established in accordance with Article 59(1) for having endocrine disrupting properties.
PBT and vPvB substance
To our knowledge, the substance or mixture does not contain any substances >0.1% that meet the criteria for persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Annex XIII.

Section 3 – Composition/information on ingredients

3.2 Mixtures
Synonyms: A formulation of SaponiQx's proprietary saponin STIMULON® QS-21, cultured plant cell QS-21 adjuvant.

STIMULON® is a registered trademark of Agenus Inc., the parent company of SaponiQx Inc.

Name	CAS Number	Classification according to Regulation (EC) No 1272/2008 [CLP] and GHS	Pictograms	Specific Concentration limits, M-Factors, Acute Toxicity Estimates (ATE)
QS-21 V2 isomer: QS-21-xylose	250643-56-2	Eye Irrit. 2; STOT SE 3; H319, H335. For full H statements see section 16.		-
QS-21 V1 isomer: QS-21-apiose	141256-04-4	Eye Irrit. 2; STOT SE 3; H319, H335. For full H statements see section 16.		-

Section 4 – First aid measures

4.1 Description of first aid measures
General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
If inhaled: Remove to fresh air. If not breathing, give artificial respiration. Consult a physician.
In case of skin contact: Wash skin with soap and plenty of water. Consult a physician.
In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
If ingested: Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed
No data available

Section 5 – Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Use water spray, carbon dioxide, dry chemical powder, or appropriate foam.
Unsuitable extinguishing media: None identified.

5.2 Special hazards arising from the substance or mixture
No information available

5.3 Advice for firefighters
Wear self-contained breathing apparatus for firefighting if necessary.

Section 6 – Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
6.1.1. For non-emergency personnel
Wear appropriate protective equipment and clothing during clean-up. For further information refer to section 8: "Exposure controls/personal protection". Ventilate spillage area.
6.1.2. For emergency responders
Wear appropriate protective equipment and clothing during clean-up. For further information refer to section 8: "Exposure controls/personal protection". Evacuate unnecessary personnel. Avoid direct contact with the spilled substance. Ensure adequate ventilation, especially in confined areas.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and material for containment and cleaning up
Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal according to local regulations (see section 13).

6.4 Reference to other sections
For disposal see section 13.

Section 7 – Handling and storage

7.1 Precautions for safe handling
Provide appropriate exhaust ventilation at places where dust is formed.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities
Store locked up. Store in a well-ventilated place. Keep container tightly closed.
Recommended storage temperature: -20°C.

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

Section 8 – Exposure controls/personal protection

8.1 Control parameters
8.1.1 National occupational exposure and biological limit values
No information available
8.1.2 Recommended monitoring procedures
No information available

8.1.3 Air contaminants formed
No information available
8.1.4 DNEL and PNEC
No information available
8.1.5 Control banding
No information available

8.2 Exposure controls
8.2.1 Appropriate engineering controls
General industrial hygiene practice.
8.2.2 Individual protection measures, such as personal protective equipment

Eye and face protection
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Respiratory protection
Respiratory protection is not required for normal conditions of use. Where protection from nuisance levels of dusts is desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards
No information available

8.2.3 Environmental exposure controls
Do not let product enter drains.

Section 9 – Physical and chemical properties

9.1 Information on basic physical and chemical properties
Physical state: Solid
Color: White
Odor/Odor threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flammability: No data available
Lower and upper explosion limit: No data available
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: No data available
Kinematic viscosity: No data available
Solubility: 1 mg/ml in phosphate buffer saline (PBS) or H_20. If resuspended in H_20, sonicate and heat at 37°C for 5 to 10 min.
Partition coefficient n-octanol/water (log value): No data available
Vapor pressure: No data available
Density and/or relative density: No data available
Relative vapor density: No data available
Particle characteristics: No data available

9.2 Other information
9.2.1 Information with regard to physical hazard classes
No data available
9.2.1 Other safety characteristics
No data available

Section 10 – Stability and reactivity

10.1 Reactivity: No data available
10.2 Chemical stability: Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions: No data available
10.4 Conditions to avoid: No data available
10.5 Incompatible materials: No data available
10.6 Hazardous decomposition products: No data available

Section 11 – Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
The toxicity data disclosed in this SDS is publicly available data for QS-21, adjuvants reported to contain QS-21, as well as *Quillaja* extracts and saponins where applicable.
Acute toxicity:
Oral LD50: No data available
Inhalation LC50: No data available
Dermal LD50: No data available
Other information on acute toxicity: QS-21 showed very low toxicity in mice when administered by intradermal immunization. Reference: Kensil *et al*., 1991. Separation and characterization of saponins with adjuvant activity from *Quillaja saponaria* Molina cortex. J Immunol. 146(2):431-7.
Skin corrosion/irritation: No data available
Serious eye damage/irritation: Saponins are eye irritants. Reference: Grant, W. M. Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974., p. 897.
Respiratory or skin sensitization: One case of occupational asthma following exposure to *Quillaja* bark dust has been reported in the literature. However, only nasal symptoms were observed on being exposed to the purified saponin. Reference: P.K. Raghuprasad *et al*., 1980. *Quillaja* bark (soapbark)--induced asthma. J Allergy Clin Immunol. 65(4):285-7.
Germ cell mutagenicity: QS-21 did not reveal genotoxicity *in vitro* or *in vivo* studies. Reference: US FDA (2017) Summary basis for regulatory action – SHINGRIX.
Carcinogenicity: *Quillaja* extracts were not carcinogenic in long-term dietary studies conducted in rats. Reference: J.J. Drake *et al*., 1982. Long-term toxicity study *quillaia* extract in rats. Food Chem Toxicol. 20(1):15-23.
Reproductive toxicity:
For an adjuvant containing up to 200 µg/ml QS-21:
Female rats were administered an adjuvant containing up to 200 µg/ml QS-21 by intramuscular (im) injection 4 and 2 weeks prior to mating, on gestation days (GD) 3, 8, 11, and 15, and on lactation day (LD) 7. The total dose was 0.2 ml on each occasion. No adverse effects on pre-weaning development up to post-natal day 25 were observed. There were no vaccine-related fetal malformations. Reference: US FDA (2020). Toxicology Review of Zoster (non-live) Vaccine, supplement 398. Cited data source: BLA rat DART study (study number: HEY0005)
A rabbit DART study was conducted to investigate the potential influence of a full human dose of an adjuvant containing up to 200 µg/ml QS-21 on fertility parameters, embryo-fetal and pre- and post-natal survival, and development of the offspring. Rabbits received saline or the full human dose of an adjuvant containing up to 200 µg/ml QS-21 by im injection 28 and 14 days prior to mating, on GD 3, 11, 16, and 24, and after natural delivery on LD 7. There were no adjuvant-related effects on clinical signs, dermal observations, or necropsy observations in the dams. There were no adjuvant-related effects on mating and female fertility, embryo-fetal pre- and post-natal survival, growth, or development. No adverse effects on pre-weaning development up to post-natal day 35 were observed. Reference: US FDA (2020). Toxicology Review of Zoster (non-live) Vaccine, supplement 398.
STOT-single exposure: No data available

STOT-repeated exposure:
For *Quillaja Saponaria* extract
Rat oral no observed adverse effect level (NOAEL) = 1500 mg/kg Reference: J.J. Drake *et al*., 1982. Long-term toxicity study quillaia extract in rats. Food Chem Toxicol. 20(1):15-23.
Mouse oral NOAEL = 700 mg/kg Reference: J.C. Phillips *et al*., 1979. Long-term toxicity study of *quillaia* extract in mice. Food Cosmet Toxicol. 17(1):23-7.
Effects: Reduced weight gain at higher doses.
No target organ effects were reported in long-term dietary studies.

Aspiration hazard: No data available

11.2 Information on other hazards
Endocrine disrupting properties: No data available
Other information: No data available

Section 12 – Ecological information

12.1 Toxicity: No data available
12.2 Persistence and degradability: No data available
12.3 Bioaccumulative potential: No data available
12.4 Mobility in soil: No data available
12.5 Results of PBT and vPvB assessment: PBT/vPvB assessment not available as chemical safety assessment not required or not conducted.
12.6 Endocrine disrupting properties: No data available
12.7 Other adverse effects: No data available

Section 13 – Disposal considerations

13.1 Waste treatment methods
Product: Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Must not be disposed of together with household garbage.
Contaminated Packaging: Dispose of as unused product.

Section 14 – Transport information

14.1 UN number
ADR/RID: - DOT (US): - IMDG: - IATA: -

14.2 UN proper shipping name
not dangerous goods

14.3 Transport hazard class(es)
ADR/RID: - DOT (US): - IMDG: - IATA: -

14.4 Packing group
ADR/RID: - DOT (US): - IMDG: - IATA: -

14.5 Environmental hazards
ADR/RID: no DOT (US): no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user
no data available

14.7 Maritime transport in bulk according to IMO instruments
not applicable

Section 15 – Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 (REACH) including the amendment to Annex II by Regulation (EU) 2020/878.

15.2 Chemical safety assessment
no data available

Section 16 – Other information

Full text of abbreviations and H-Statements referred to in sections 2 and 3.

Eye Irrit.	Eye irritation
STOT SE	Specific target organ toxicity - single exposure

H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

The information contained in this SDS relates only to the material(s) designated and does not relate to use(s) in combination with any other material, process(es) and/or chemical reaction(s). InvivoGen provides this information in good faith and is based on our present knowledge. This SDS is provided without warranty of any kind. The recipient is responsible for ensuring that, where applicable, existing laws and guidelines are observed.