According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 06.04.2024 11207350-00003 Date of first issue: 27.04.2023 1.2

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

1.1 Product identifier

Trade name : ProQuad Formulation

Product code : Measles, Mumps, Rubella, and Varicela Vaccine Live

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

Use of the Sub-

stance/Mixture

: Pharmaceutical

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company MSD

120 Moorgate

EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

## 1.4 Emergency telephone number

1-908-423-6000

## **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Not a hazardous substance or mixture.

## 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

EUH210 Safety data sheet available on request.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.2
 06.04.2024
 11207350-00003
 Date of first issue: 27.04.2023

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air during processing, handling or other means.

## **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

## Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)	
Antigen	Not Assigned		>= 1 - < 10	
Neomycin, sulfate (salt)	1405-10-3 215-773-1	Skin Sens. 1B; H317 Repr. 2; H361d STOT RE 2; H373 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——— M-Factor (Acute aquatic toxicity): 1,000 M-Factor (Chronic aquatic toxicity): 10	>= 0.0025 - < 0.025	
Substances with a workplace exposure limit :				
Sucrose	57-50-1 200-334-9		>= 50 - < 70	

For explanation of abbreviations see section 16.

### **SECTION 4: First aid measures**

## 4.1 Description of first aid measures

Protection of first-aiders : No special precautions are necessary for first aid responders.

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap.

Get medical attention if symptoms occur.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

Chlorine compounds

5.3 Advice for firefighters

Special protective equipment :

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary. Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

# **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.2
 06.04.2024
 11207350-00003
 Date of first issue: 27.04.2023

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-

nated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store in accordance with

the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

## **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	TWA	10 mg/m3	GB EH40
		STEL	20 mg/m3	GB EH40
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (OEB 1)	Internal
	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal

## **Derived No Effect Level (DNEL):**

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m3
	Workers	Inhalation	Acute systemic effects	2068.62 mg/m3
	Workers	Skin contact	Long-term systemic effects	295.52 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	295.52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443.28 mg/m3
	Consumers	Inhalation	Acute systemic effects	443.28 mg/m3

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.2
 06.04.2024
 11207350-00003
 Date of first issue: 27.04.2023

	Consumers	Skin contact	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	126.65 mg/kg bw/day

## **Predicted No Effect Concentration (PNEC):**

Substance name	Environmental Compartment	Value
Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4.86 mg/kg dry
		weight (d.w.)
Neomycin, sulfate (salt)	Water	0.00004 mg/l

#### 8.2 Exposure controls

## **Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

## Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions.

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to BS EN 143

Filter type : Particulates type (P)

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Appearance : solid Colour : white

light vellow

Odour : No data available
Odour Threshold : No data available

pH : 6.6 - 7.1

Melting point/freezing point : No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

Initial boiling point and boiling

range

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air during pro-

cessing, handling or other means.

Upper explosion limit / Upper

flammability limit

No data available

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : No data available

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form combustible dust concentrations in air during pro-

cessing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

## 11.1 Information on toxicological effects

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion

Eye contact

## **Acute toxicity**

Not classified based on available information.

### Components:

# Neomycin, sulfate (salt):

Acute oral toxicity : LD50 (Mouse): 2,880 mg/kg

LD50 (Rat): 2,750 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): 633 mg/kg

Application Route: Subcutaneous

LD50 (Mouse): 116 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 27.6 mg/kg Application Route: Intravenous

LD50 (Mouse): 275 mg/kg

Application Route: Subcutaneous

Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

## Neomycin, sulfate (salt):

Species : Rabbit

Result : Mild skin irritation

## Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

#### Neomycin, sulfate (salt):

Species : Rabbit

Result : No eye irritation

## Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

#### Neomycin, sulfate (salt):

Exposure routes : Dermal Species : Humans Result : positive

## Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

## Neomycin, sulfate (salt):

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Result: negative

Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: positive

Test Type: in vitro micronucleus test

Result: negative

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

Genotoxicity in vivo : Test Type: Cytogenetic assay

Species: Mouse

Cell type: Bone marrow

Application Route: Intravenous injection

Result: negative

Sucrose:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Neomycin, sulfate (salt):

Species : Rat
Exposure time : 2 Years
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Neomycin, sulfate (salt):

Effects on fertility : Test Type: Three-generation reproduction toxicity study

Species: Rat

Application Route: Oral

General Toxicity - Parent: NOAEL: 25 mg/kg body weight Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Embryo-foetal toxicity: NOAEL: 275 mg/kg body weight Result: No adverse effects, No teratogenic effects

Test Type: Development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 6 mg/kg body weight

Result: positive

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

STOT - single exposure

Not classified based on available information.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

#### STOT - repeated exposure

Not classified based on available information.

#### **Components:**

## Neomycin, sulfate (salt):

Target Organs : Kidney, inner ear

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Remarks : Based on human experience.

#### Repeated dose toxicity

#### **Components:**

## Neomycin, sulfate (salt):

Species : Mouse LOAEL : 30 mg/kg Application Route : Subcutaneous

Exposure time : 14 d
Target Organs : Kidney

Species : Guinea pig
NOAEL : 50 mg/kg
LOAEL : 100 mg/kg
Application Route : Intramuscular
Exposure time : 30 - 60 Weeks

Target Organs : ear

Species : Guinea pig
NOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 90 d

Remarks : No significant adverse effects were reported

Species : Guinea pig LOAEL : 100 mg/kg Application Route : Subcutaneous

Exposure time : 34 d

Species : Dog LOAEL : 24 mg/kg Application Route : Intramuscular

Exposure time : 30 d
Target Organs : Kidney

Species : Rat
LOAEL : 25 mg/kg
Application Route : oral (feed)
Exposure time : 84 Weeks
Target Organs : ear

Target Organs : ear

Symptoms : hearing loss Remarks : mortality observed

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 06.04.2024 11207350-00003 Date of first issue: 27.04.2023 1.2

**Species** Dog LOAEL 20 mg/kg Subcutaneous Application Route

Exposure time 90 d Target Organs Kidney

#### **Aspiration toxicity**

Not classified based on available information.

## **Experience with human exposure**

#### **Components:**

#### Neomycin, sulfate (salt):

Symptoms: Sensitisation Skin contact

Remarks: May irritate skin.

Eve contact Remarks: May cause eye irritation.

Ingestion Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing

loss, Loss of balance

#### **SECTION 12: Ecological information**

# 12.1 Toxicity

#### **Components:**

## Neomycin, sulfate (salt):

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 72 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

LC50 (Americamysis): 39 mg/l

Exposure time: 96 h

Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)):

0.0022 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

M-Factor (Acute aquatic tox- :

icity)

1,000

Toxicity to microorganisms : EC50 (Natural microorganism): 107.6 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

EC10 (Natural microorganism): 2.8 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

M-Factor (Chronic aquatic

toxicity)

10

#### 12.2 Persistence and degradability

#### **Components:**

Neomycin, sulfate (salt):

Biodegradability : Result: rapidly degradable

Biodegradation: 50 % Exposure time: 1.2 d

Method: OECD Test Guideline 314

#### 12.3 Bioaccumulative potential

#### **Components:**

Neomycin, sulfate (salt):

Partition coefficient: n-

octanol/water

: log Pow: < -2

Sucrose:

Partition coefficient: n-

octanol/water

: Pow: < 1

## 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

## **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Other adverse effects

#### **Product:**

Endocrine disrupting poten : This substance/mixture does not contain components consid-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

tial ered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## **SECTION 14: Transport information**

#### 14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

## 14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable UK REACH Candidate list of substances of very high : Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) No 1005/2009 on substances that de- : Not applicable

plete the ozone layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Not applicable

## The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

Not applicable

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.2 06.04.2024 11207350-00003 Date of first issue: 27.04.2023

lines.

#### **Full text of H-Statements**

H317 : May cause an allergic skin reaction.
H361d : Suspected of damaging the unborn child.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **ProQuad Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.2
 06.04.2024
 11207350-00003
 Date of first issue: 27.04.2023

#### **Further information**

Sources of key data used to compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN