

# SAFETY DATA SHEET



## ProQuad Formulation

Version 2.0      Revision Date: 14.04.2025      SDS Number: 11206666-00006      Date of last issue: 25.02.2025  
Date of first issue: 27.04.2023

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### SECTION 1: IDENTIFICATION

Product name : ProQuad Formulation  
Product code : Measles, Mumps, Rubella, and Varicela Vaccine Live

#### Manufacturer or supplier's details

Company : MSD  
Address : Building A - Level 1/26 Talavera Rd  
Macquarie Park NSW, Australia 2113  
Telephone : 1 800 033 461  
Emergency telephone number : Poisons Information Centre: Phone 13 11 26  
E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Not a hazardous substance or mixture.

#### GHS label elements

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

#### Other hazards which do not result in classification

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.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 30 -< 60
Antigen	Not Assigned	< 10
Neomycin, sulfate (salt)	1405-10-3	< 1

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### SECTION 4. FIRST AID MEASURES

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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.
In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	: No special precautions are necessary for first aid responders.
Notes to physician	: Treat symptomatically and supportively.

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## SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NOx) Metal oxides Chlorine compounds
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances 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.
Special protective equipment for firefighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so.

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Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up :

- Sweep up or vacuum up spillage and collect in suitable container 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 determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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## SECTION 7. HANDLING AND STORAGE

Technical measures	<ul style="list-style-type: none"><li>Static electricity may accumulate and ignite suspended dust causing an explosion.</li><li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li></ul>
Local/Total ventilation	<ul style="list-style-type: none"><li>Use only with adequate ventilation.</li></ul>
Advice on safe handling	<ul style="list-style-type: none"><li>Do not breathe dust.</li><li>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</li><li>Minimize dust generation and accumulation.</li><li>Keep container closed when not in use.</li><li>Keep away from heat and sources of ignition.</li><li>Take precautionary measures against static discharges.</li><li>Take care to prevent spills, waste and minimize release to the environment.</li></ul>
Hygiene measures	<ul style="list-style-type: none"><li>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</li><li>When using do not eat, drink or smoke.</li><li>Wash contaminated clothing before re-use.</li><li>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.</li></ul>
Conditions for safe storage	<ul style="list-style-type: none"><li>Keep in properly labelled containers.</li><li>Store in accordance with the particular national regulations.</li></ul>
Materials to avoid	<ul style="list-style-type: none"><li>Do not store with the following product types:</li><li>Strong oxidizing agents</li></ul>

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	AU OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Neomycin, sulfate (salt)	1405-10-3	TWA	1.5 mg/m <sup>3</sup> (OEB 1)	Internal
Further information: DSEN, OTO				
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal

**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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Eye 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.

Skin and body protection : Work uniform or laboratory coat.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Colour : white

Odour : light yellow

Odour Threshold : No data available

pH : 6.6 - 7.1

Melting point/freezing point : No data available

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Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air during processing, handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : 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-octanol/water : Not applicable

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.

Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

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Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation Skin contact Ingestion Eye contact
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### Acute toxicity

Not classified based on available information.

### Components:

#### **Sucrose:**

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

### **Skin corrosion/irritation**

Not classified based on available information.

### Components:

#### **Neomycin, sulfate (salt):**

Species	: Rabbit
Result	: Mild skin irritation

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### **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

### **Chronic toxicity**

#### **Germ cell mutagenicity**

Not classified based on available information.

#### **Components:**

##### **Sucrose:**

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
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##### **Neomycin, sulfate (salt):**

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

Genotoxicity in vivo	:	Test Type: Cytogenetic assay Species: Mouse
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Cell type: Bone marrow  
Application Route: Intravenous injection  
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 development were detected.

Effects on foetal development : 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 - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.

### Components:

#### **Neomycin, sulfate (salt):**

Target Organs : Kidney, inner ear

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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
Symptoms	: hearing loss
Remarks	: mortality observed
Species	: Dog
LOAEL	: 20 mg/kg
Application Route	: Subcutaneous
Exposure time	: 90 d
Target Organs	: Kidney

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### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **Neomycin, sulfate (salt):**

Skin contact	: Symptoms: Sensitisation Remarks: May irritate skin.
Eye contact	: Remarks: May cause eye irritation.
Ingestion	: Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Neomycin, sulfate (salt):**

Toxicity to daphnia and other aquatic invertebrates	: 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
Toxicity to microorganisms	: EC50 (Natural microorganism): 107.6 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

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EC10 (Natural microorganism): 2.8 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **Neomycin, sulfate (salt):**

Biodegradability : Result: rapidly degradable  
Biodegradation: 50 %  
Exposure time: 1.2 d  
Method: OECD Test Guideline 314

### Bioaccumulative potential

#### Components:

##### **Sucrose:**

Partition coefficient: n-octanol/water : Pow: < 1

##### **Neomycin, sulfate (salt):**

Partition coefficient: n-octanol/water : log Pow: < -2

### Mobility in soil

No data available

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

#### **International Regulations**

##### **UNRTDG**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable

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Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### ADG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons Standard) Instrument : Schedule 6 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of

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the model WHS Act and Regulations.

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

AICS : not determined  
DSL : not determined  
IECSC : not determined

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## SECTION 16: ANY OTHER RELEVANT INFORMATION

### **Further information**

Revision Date : 14.04.2025  
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 Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

### **Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.  
  
ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-

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ment; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

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