

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Creation Date 09-Sep-2014

Revision Date 29-Sep-2023

Revision Number 9

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

 Product Description:
 Hydrocortisone

 Cat No.:
 352450000; 352450010; 352450050

 Synonyms
 11beta,17alpha,21-Trihydroxypregn-4-ene-3,20-dione

 CAS No
 50-23-7

 EC No
 200-020-1

 Molecular Formula
 C21 H30 Q5

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

Recommended Use	Laboratory chemicals.
Uses advised against	No Information available

1.3. Details of the supplier of the safety data sheet

Company

UK entity/business name Fisher Scientific UK Bishop Meadow Road, Loughborough, Leicestershire LE11 5RG, United Kingdom

EU entity/business name Thermo Fisher Scientific

Janssen Pharmaceuticalaan 3a, 2440 Geel, Belgium

E-mail address

begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

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Category 1A (H360Df)

Category 2 (H373)

Reproductive Toxicity Specific target organ toxicity - (repeated exposure)

Environmental hazards

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

2.2. Label elements



Signal Word

Danger

Hazard Statements

H360Df - May damage the unborn child. Suspected of damaging fertility H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements

P201 - Obtain special instructions before use
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention

Additional EU labelling

Restricted to professional users

2.3. Other hazards

This product does not contain any known or suspected endocrine disruptors

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-	50-23-7	EEC No. 200-020-1	>95	Repr. 1A (H360Df) STOT RE 3 (H373)

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice	If symptoms persist, call a physician.	
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.	
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.	
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.	
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.	
Self-Protection of the First Aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.	
4.2. Most important symptoms and effects, both acute and delayed		
	None reasonably foreseeable.	
4.3. Indication of any immediate medical attention and special treatment needed		

Notes to Physician

Hydrocortisone

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO₂).

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

6.2. Environmental precautions

Should not be released into the environment.

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6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep container tightly closed. Protect from light. Protect from direct sunlight.

Technical Rules for Hazardous Substances (TRGS) 510Class 6.1CStorage Class (LGK) (Germany)

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

No information available

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equencies Eye Protection		(European standard	1 - EN 166)	
Hand Protection	Protectiv	ve gloves		
Glove material Nitrile rubber Neoprene Natural rubber PVC	Breakthrough time See manufacturers recommendations	Glove thickness -	EU standard EN 374	Glove comments (minimum requirement)
Skin and body prote	ection Long sle	eved clothing.		

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly
Large scale/emergency use	Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced Recommended Filter type: Particulates filter conforming to EN 143
Small scale/Laboratory use	Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Recommended half mask:- Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State	Powder Solid
Appearance	White
Odor	No information available
Odor Threshold	No data available
Melting Point/Range	212 - 217 °C / 413.6 - 422.6 °F
Softening Point	No data available
Boiling Point/Range	No information available

Flammability (liquid)	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
		
Flash Point	No information available	Method - No information available
Autoignition Temperature	Not applicable	
Decomposition Temperature	No data available	
рН	No information available	
Viscosity	Not applicable	Solid
Water Solubility	Insoluble	practically insoluble
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/wa	ter)	
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	No data available	
Vapor Density	Not applicable	Solid
Particle characteristics	No data available	
9.2. Other information		
3.2. Other information		
Molecular Formula	C21 H30 O5	

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity	None known, based on information available	
10.2. Chemical stability	Stable under normal conditions. Light sensitive.	
10.3. Possibility of hazardous reactions		
Hazardous Polymerization Hazardous Reactions	Hazardous polymerization does not occur. None under normal processing.	
10.4. Conditions to avoid	Exposure to light. Incompatible products. Exposure to moist air or water.	
10.5. Incompatible materials	Strong oxidizing agents.	

10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

362.47

Not applicable - Solid

Product Information

Hydrocortisone

Molecular Weight

Evaporation Rate

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(b) skin corrosion/irritation;	No data available
(c) serious eye damage/irritation;	No data available
(d) respiratory or skin sensitization; Respiratory Skin	No data available No data available
(e) germ cell mutagenicity;	No data available
(f) carcinogenicity;	No data available
	There are no known carcinogenic chemicals in this product
(g) reproductive toxicity; Teratogenicity	Category 1A Teratogenic effects have occurred in experimental animals.
(h) STOT-single exposure;	No data available
(i) STOT-repeated exposure;	Category 2
Target Organs	None known.
(j) aspiration hazard;	Not applicable Solid
Other Adverse Effects	The toxicological properties have not been fully investigated.
Symptoms / effects,both acute and delayed	No information available.
11.2. Information on other hazards	

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity Ecotoxicity effects

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system. Do not empty into drains.

12.2. Persistence and degradability	
Persistence	Insoluble in water.

12.3. Bioaccumulative potential May have some potential to bioaccumulate

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<u>12.4. Mobility in soil</u>	Spillage unlikely to penetrate soil Is not likely mobile in the environment due its low water solubility.
12.5. Results of PBT and vPvB assessment	No data available for assessment.
12.6. Endocrine disrupting properties Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors
<u>12.7. Other adverse effects</u> Persistent Organic Pollutant Ozone Depletion Potential	This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues/Unused Products	Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.
Contaminated Packaging	Dispose of this container to hazardous or special waste collection point.
European Waste Catalogue (EWC)	According to the European Waste Catalog, Waste Codes are not product specific, but application specific.
Other Information	Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

Not regulated

14.1. UN number14.2. UN proper shipping name14.3. Transport hazard class(es)14.4. Packing group

ADR

Not regulated

14.1. UN number14.2. UN proper shipping name14.3. Transport hazard class(es)14.4. Packing group

<u>IATA</u>

Not regulated

<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> <u>14.3. Transport hazard class(es)</u>

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14.4. Packing group

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods

SECTION 15: REGULATORY INFORMATION

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

International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
Pregn-4-ene-3,20-dione,	50-23-7	200-020-1	-	-	Х	Х	KE-34304	Х	Х
11,17,21-trihydroxy-, (11.beta.)-									

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-	50-23-7	Х	ACTIVE	Х	-	Х	Х	-

Legend: X - Listed '-' - Not Listed

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Not applicable

Authorisation/Restrictions according to EU REACH

REACH (1907/2006) -REACH (1907/2006) -**REACH Regulation (EC** Component CAS No Annex XIV - Substances Annex XVIÌ - Restrictions 1907/2006) article 59 Candidate List of Subject to Authorization on Certain Dangerous Substances Substances of Very High Concern (SVHC) Pregn-4-ene-3,20-dione, 50-23-7 -11,17,21-trihydroxy-, (11.beta.)-

Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-	50-23-7	Not applicable	Not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

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Take note of Directive 94/33/EC on the protection of young people at work Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

WGK Classification

See table for values

Component	Germany - Water Classification (AwSV)	Germany - TA-Luft Class
Pregn-4-ene-3,20-dione,	WGK2	
11,17,21-trihydroxy-, (11.beta.)-		

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H360Df - May damage the unborn child. Suspected of damaging fertility H373 - May cause damage to organs through prolonged or repeated exposure

Legend

CAS - Chemical Abstracts Service EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances PICCS - Philippines Inventory of Chemicals and Chemical Substances IECSC - Chinese Inventory of Existing Chemical Substances KECL - Korean Existing and Evaluated Chemical Substances	TSCA - United States Toxic Substances Control Act Section 8(b) Inventory DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances NZIOC - New Zealand Inventory of Chemicals
WEL - Workplace Exposure Limit ACGIH - American Conference of Governmental Industrial Hygienists DNEL - Derived No Effect Level RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50% NOEC - No Observed Effect Concentration PBT - Persistent, Bioaccumulative, Toxic	 TWA - Time Weighted Average IARC - International Agency for Research on Cancer Predicted No Effect Concentration (PNEC) LD50 - Lethal Dose 50% EC50 - Effective Concentration 50% POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative
ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code OECD - Organisation for Economic Co-operation and Development BCF - Bioconcentration factor Key literature references and sources for data https://echa.europa.eu/information-on-chemicals Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, R	ICAO/IATA - International Civil Aviation Organization/International Air Transport Association MARPOL - International Convention for the Prevention of Pollution from Ships ATE - Acute Toxicity Estimate VOC - (Volatile Organic Compound)

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit

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and standards. First aid for chemical exposure, including the use of eye wash and safety showers.

Creation Date
Revision Date
Revision Summary

09-Sep-2014 29-Sep-2023 Not applicable.

This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.

Disclaimer

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

End of Safety Data Sheet