

SECTION 1: IDENTIFICATION		
1.1 Product identifier		
Product name:	Felimazole <sup>®</sup> (Coated Tablets for cats) EU: 1.25mg, 2.5mg and 5mg US: 2.5mg and 5mg	
Synonyms:	Thiourelyne antithyroid agent	
Proper Shipping name:	Not applicable	
Other means of identification:	None	
1.2 Relevant identified uses	s of the substances or mixture and uses advised against	
Recommended uses:	For use in cats. For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy. For the long term treatment of feline hyperthyroidism.	
Uses advised against:	<ul> <li>As thiamazole is a suspected human teratogen, pregnant women, and women of child-bearing age, should wear gloves when handling the product or the litter used by treated animals. Do not handle this product if you are allergic to hyperthyroidism inhibitors.</li> <li>Do not use in cats suffering from systemic disease such as primary liver disease or diabetes mellitus.</li> <li>Do not use in cats showing signs of autoimmune disease.</li> <li>Do not use in animals with disorders of white blood cells, such as neutropenia and lymphopenia.</li> <li>Do not use in cats with platelet disorders and coagulopathies (particularly thrombocytopenia).</li> <li>Do not use in cats with hypersensitivity to thiamazole or the excipient, polyethylene glycol.</li> <li>Do not use in pregnant or lactating females.</li> </ul>	
1.3 Details of the supplier o	f the substance or mixture	
Registered company name (UK):	Dechra Ltd	
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK	
Telephone:	+44 (0) 1756 791311	



+44 (0) 1756 798604	
www.dechra.com	
Not available	
Dechra Veterinary Products	
Dechra Pharmaceutical Products 7015 College Blvd Suite 525 Overland Park KS 66211 USA	
866-933-2472	
Not available	
www.dechra.com	
Not available	
1.4 Emergency Telephone Numbers	
866-933-2472	

SECTION 2: HAZARDS IDENTIFICATION		
2.1 Classification of the substance or mixture Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).		
Considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes (US).		
regulation (EC) No	<ul> <li>H302 - Acute Toxicity (Oral) Category 4</li> <li>H341 - Gender Cell Mutagenic Substances of Category 2</li> <li>H361 - Reproductive Toxicity 2</li> <li>H335 - STOT - SE (No. Irr) Category 3</li> </ul>	
Legend:	1. Classified by Chemwatch	
Classification (US):	Acute Toxicity (Oral) Category 4, Germ cell mutagenicity Category 2, Reproductive Toxicity Category 2, Specific target organ toxicity – single exposure Category 3 (respiratory tract irritation)	
2.2 Label Elements		
GHS Label Elements:		
Signal Word:	WARNING	



Hazard statement(s):		
H302	Harmful if swallowed.	
H341	Suspected of causing genetic defects.	
H361	Suspected of damaging fertility or the unborn child.	
H335	May cause respiratory irritation.	
Precautionary Statement(s)	Prevention:	
P201	Obtain special instructions before use.	
P271	Use only outdoors or in a well-ventilated area.	
P261	Avoid breathing dust/fumes.	
P280	Wear protective gloves/protective clothing/eye protection/face protection.	
P270	Do not eat, drink or smoke when using this product.	
Precautionary Statement(s)	Response:	
P308 + P313	IF exposed or concerned: Get medical advice/attention.	
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.	
P330	Rinse mouth.	
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.	
Precautionary Statement(s)	Storage:	
P405	Store locked up.	
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.	
Precautionary Statement(s) Disposal:		
P501	Dispose of contents/container in accordance with local regulations.	
(SVHC) on SDS date printing.	ative effects *.	

(SVHC) at the SDS print date.



## **SECTION 3: INFORMATION ON THE INGREDIENTS**

### 3.1 Substances

See section below for composition of mixtures

3.2 Mixtures			
1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 60-56-0 2. 200-482-4 3. Not Available 4. Not Available	2.5-5	Thiamazole (EU) Methimazole (US)	Acute toxicity (oral) Category 4, gender cell mutagenic substance of category 2, reproductive toxicity 2; H302, H341, H361 <sup>[1]</sup>
	Balance	Ingredients determined not to be hazardous	
Legend:	1. Classified by Chemwatch		

SECTION 4: FIRST AID MEASURES		
4.1 Description of first a	4.1 Description of first aid measures	
Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.	
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner. Wash hands with soap and water after handling litter used by treated animals. As thiamazole is a suspected human teratogen, pregnant women, and women of child-bearing age, should wear gloves when handling the product or the litter used by treated animals.	
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.	
Ingestion:	IF SWALLOWED, SEEK MEDICAL ATTENTION WITHOUT DELAY. For advice, contact a Poisons Information Centre or a medical	

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L In s t V V V L L I I I I I I I I I I I I I I I	bractitioner. Jrgent hospital treatment is likely to be needed. If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise: NDUCE vomiting with fingers down the back of the throat, ONLY F CONSCIOUS. Lean patient forward or place on left side (head- down position, if possible) to maintain open airway and prevent aspiration. NOTE: Wear a protective glove when inducing vomiting by nechanical means.		
4.2 Most important symp	toms and effects, both acute and delayed		
pancytopenia. Treatment is	Thiamazole may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritus and pancytopenia. Treatment is symptomatic. For more information see Section 11		
If blood disorders such as a	te medical attention and special treatment needed agranulocytosis or bone-marrow depression occur exposure must accessary, antibiotics and blood transfusions may be		
Legend: MARTINDALE: The Extra Pharmacopoeia, 29th Edition			
SECTION 5: FIRE FIGHTING MEASURES			
5.1 Extinguishing media			
Suitable:	Select extinguishing media suitable for surrounding area.		
Unsuitable:	There is no restriction on the type of extinguisher which may be used.		
5.2 Special hazards arisir	ng from the substance or mixture		
Fire incompatibility:	None known.		



5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. <b>DO NOT</b> approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn. Decomposition may produce toxic fumes of: Sulphur oxides (SOx). May emit poisonous fumes. May emit corrosive fumes.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

## 6.1 Personal precautions, protective equipment and emergency procedures

For information on protective equipment, see section 8

#### 6.2 Environmental Precautions

See section 12

**6.3 Methods and material for containment and cleaning up** Spills are unlikely due to the nature of the product and how it is packaged

Minor Spills:	Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal.
Major Spills:	Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses.



SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Wear suitable clothing when risk of exposure occurs. Do not eat, drink or smoke while handling the tablet or used litter. Wash hands with soap and water after handling litter used by treated animals. Observe manufacturer's storage and handling recommendations.
Other Information:	Store in original containers in a cool, dry area. Keep containers securely sealed. Do not break or crush tablets. Keep out of the reach and sight of children.
7.2 Conditions for safe sto	orage, including any incompatibilities
Suitable Container:	Keep the container tightly closed in order to protect from moisture. Tablets stored in a white polypropylene tub with white low density polyethylene tamper evident lid containing 100 tablets. Keep the container in the outer carton. Do not store above 25°C. Check all containers are clearly labelled and free from leaks. Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Storage incompatibility:	None known.
7.3 Specific end uses	
Not available	

## **SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

#### 8.1 Control parameters

## DERIVED NO EFFECT LEVEL - DNEL (EU)

Not Available

## PREDICTED NO EFFECT LEVEL - PNEC (EU)

Not Available

## OCCUPATIONAL EXPOSURE LIMITS (OEL)

## **INGREDIENT DATA (EU):**

Not Available



INGREDIENT DATA (US):	
Not Available	
EMERGENCY LIMITS (EU/US):	
Not Available	
8.2 Exposure controls	
	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
Personal protection:	
Eye and face protection:	Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves. As thiamazole is a suspected human teratogen, pregnant women, and women of child-bearing age, should wear gloves when handling the product or the litter used by treated animals.
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not available
Respiratory protection:	Not applicable
8.3 Environmental exposure controls See Section 12	



#### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES 9.1 Information on basic physical and chemical properties Appearance: Active: A white or pale brown crystalline powder. Tablet: Red sugar-coated biconvex tablets 5.5 mm diameter. **Container:** White polypropylene tub with white low density polyethylene tamper evident lid containing 100 tablets. Physical state: Solid Odour: Faint characteristic odour Odour Threshold: Not available **pH (as supplied):** Solutions in water are practically neutral to litmus Melting point / freezing point (degrees C): 146°C -148°C **Initial boiling point and boiling range:** 280°C (with some decomposition) Flash Point: Not applicable Evaporation rate: Not available Flammability: Not available Upper/lower flammability or explosive limits: Not available Vapour pressure: Not available Relative Density (at degrees C): Not available Solubility in water and solvents (mg/l): Water: Soluble 1 in 5 Alcohol: Soluble 1 in 5 Chloroform: Soluble 1 in 4.5 Ether: Soluble 1 in 125 Vapour density: Not available Auto ignition temperature (degrees C): Not available **Decomposition temperature (degrees C):** Not available Viscosity: (degrees C): Not available Explosive properties: Not available Oxidising properties: Not available Partition Coefficient: Not available Molecular weight: 114.17 Taste: Not available Surface tension: Not available Volative component: Not available Gas group: Not available pH as a solution: Not available VOC g/L: Not available 9.2 Other information

Not Available

10: REACTIVITY AND STABILITY	
10.1 Reactivity:	Avoid reaction with oxidizing agents.
10.2 Chemical stability:	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of	The product is not considered to be hazardous if used as per



hazardous reactions:	instructions. Will not polymerize.	
10.4 Conditions to avoid:	Avoid heat, flame and ignition sources. May emit toxic fumes under fire conditions.	
10.5 Incompatible materials:	Unstable in the presence of incompatible materials.	
10.6 Hazardous decomposition:	See Section 5.	

SECTION 11: TOXIC	SECTION 11: TOXICOLOGICAL INFORMATION				
Inhalation:	Not normally a hazard due to the nature of product. Material can however cause respiratory irritation in some persons. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.				
Ingestion:	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.				
Skin contact:	Skin contact is not thought to produce harmful health effects. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.				
Eye contact:	Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.				
Chronic:	Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Strong evidence exists that this substance may cause irreversible mutations (though not lethal) even following a single exposure. Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.				



Felimazole Coated Tablets 1.25mg, 2.5mg, 5mg:	Toxicity	Irritation			
	Not Available	Not Available			
	Acute toxicity	Irritation			
Methimazole:	Oral (rat) LD <sub>50</sub> : 2250 mg/kgd <sup>1</sup>	May cause skin and eye irritation.			
	om manufacturer's SD ter of Toxic Effect of ch	S. Unless otherwise specified, data extracted nemical Substances			
Acute toxicity:					
vomiting, epigastric d	istress, headache, fev	although it is known that thiamazole may cause er, arthralgia, pruritis and pancytopaenia. supportive as there is no antidote.			
Skin corrosion/ irrita	ation:				
Not expected to cause	e irritation.				
Serious eye damage	e/ irritation:				
Not expected to cause irritation.					
Respiratory or skin sensitization:					
Not expected to cause irritation.					
Germ cell mutagenicity:					
Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation.					
Carcinogenicity:					
Not Available					
Reproductive toxici	ty:				
Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.					
STOT – single expo	STOT – single exposure:				
May cause respirator	y irritation.				
STOT-repeated exp	STOT–repeated exposure:				
Not available					
i tot a tanabio					



#### **SECTION 11: TOXICOLOGICAL INFORMATION**

Not available

### **SECTION 12: ECOLOGICAL INFORMATION**

12.1 Toxicity							
Felimazole Coated Tablets	Endpoint	Test Duration (Hr)	Species	Value	Source		
– 2.5mg, 5mg:	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable		
Thiamazole/	LC <sub>50</sub>	96	Fish	1274.195mg/L	3		
lethimazole:	EC <sub>50</sub>	96	Algae or other aquatic plants	9061.206mg/L	3		
	EC <sub>50</sub>	384	Crustacea	288.626mg/L	3		
	NOEC	56dpf	Fish	0.1136mg/L	4		

**DO NOT** discharge into sewer or waterways.

#### 12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air		
Thiamazole/Methimazole	LOW	LOW		
12.3 Bioaccumulative potential				

#### Bioaccumulation Ingredient Thiamazole/Methimazole LOW (LogKOW = -0.34)

#### 12.4 Mobility in Soil

Ingredient	Mobility	
Thiamazole/Methimazole	LOW (KOC = 8.088)	

#### 12.5 Results of PBT and vPvB assessment Not Available

#### 12.6 Other adverse effects

Not Available

## **SECTION 13: DISPOSAL CONSIDERATIONS**

#### 13.1 Waste treatment methods

Product / DO NOT allow wash water from cleaning or process equipment to packaging enter drains.



disposal:	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.
	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.
	Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal.
	Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available



SECTION 14: TRANSPORT INFORMATION					
Labels required:					
Marine pollutant:	NO				
Hazchem:	Not Applicable				
Land transport (EU: DANGEROUS GOOD		GULATED FOR TRANSPORT OF			
14.1 UN Number	N/a				
14.2 UN Proper Shipping Name	N/a				
14.3 Transport	Class	N/a			
hazard class(es)	Sub risk	N/a			
14.4 Packing group	N/a				
14.5 Environmental hazards	N/a				
14.6 Special	Special provisions	N/a			
precautions for user	Limited quantity	N/a			
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Annex II of MARPOL73/78 and				
Air transport (ICAO-I DANGEROUS GOOD		ATED FOR TRANSPORT OF			
14.1 UN Number	N/a				
14.2 UN Proper Shipping Name	N/a				
14.3 Transport	ICAO/IATA Class	N/a			
hazard class(es)	ICAO / IATA Sub risk	N/a			
	ERG Code	N/a			
14.4 Packing group	N/a				
14.5 Environmental hazards	N/a				
	Special provisions	N/a			
precautions for user	Cargo only packing instructions	N/a			



	Cargo only maximur qty/pack	n	N/a			
	Passenger and carg packaging instruction		N/a	-		
	Passenger and carg maximum qty/pack	0	N/a			
	Passenger and carg limited quantity pack instructions		N/a			
	Passenger and carg limited maximum qty/pack	0	N/a			
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code						
Sea transport (IMDG DANGEROUS GOOD		OT RI	EGULATED	FOR TRA	NSPORT OF	:
14.1 UN Number	N/a					
14.2 UN Proper Shipping Name	N/a					
14.3 Transport	IMDG Class	N/a				
hazard class(es)	IMDG Sub risk	N/a				
14.4 Packing group	N/a					
14.5 Environmental hazards	N/a					
	EMS Number	N/a				
precautions for user	Special provisions	N/a				
	Limited quantities	N/a				
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code						
Inland waterways tra DANGEROUS GOOD		REGL	JLATED FO	OR TRANSI	PORT OF	



14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
	Classification Code	N/a
precautions for user	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code		

#### SECTION 15: REGULATORY INFORMATION

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

# THIAMAZOLE / METHIMAZOLE (60-56-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs of Chemicals ECICS (English)
- European Union European inventory of existing chemical commodities (EINECS)
- International Agency for Cancer Research (IARC) Agents Issued by the IARC Monographs
- US International Agency for Research on Cancer (IARC) Agents Classified by the IARC Monographs
- US California Proposition 65 Reproductive Toxicity
- US Priority List for the Development of Proposition 65 Safe Harbour Levels No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity
- US Toxic Substances Control Act (TSCA) Chemical Substance Inventory

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC



### FEDERAL REGULATIONS:

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Section 311/312 Hazard Categories

Immediate (acute) health hazard	Yes
Delayed (chronic) health hazard	Yes
Fire hazard	No
Pressure hazard	No
Reactivity hazard	No

### US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None Reported

STATE REGULATIONS

#### **US. CALIFORNIA PROPOSITION 65**

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm

#### US - CALIFORNIA PREPOSITION 65 - CARCINOGENS & REPRODUCTIVE TOXICITY (CRT): LISTED SUBSTANCE

Methimazole listed

#### **15.2 Chemical Safety Assessment**

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Thiamazole	60-56-0	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Sens. 1, Repr. 2	GHS07, GHS08, Wng	H317, H361
2	Skin Sens. 1, Repr. 2, Acute Tox. 4	GHS08, Wng	H317, H361, H302, H332, H315, H335, H319

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (thiamazole/methimazole)



China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	N (thiamazole/methimazole)
USA - TSCA	Y
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)



## **SECTION 16: OTHER INFORMATION**

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

#### Full text Risk and Hazard codes:

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes severe eye irritation.
H332	Harmful if inhaled.
H361	May possibly harm the fertility of the unborn child.

Relevant risk statements are found in section 2.1

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 - Personal eye protection

EN 340 - Protective clothing

EN 374 - Protective gloves against chemicals and microorganisms

EN 13832 - Protective footwear against chemicals

EN 133 - Respiratory protection

## NFPA 704 diamond (US):



Blue = Health, Red = Fire, Yellow = Reactivity, White = Special (Oxidizer or water reactive substances)

#### **Definitions and abbreviations**

PC-TWA: Permissible Concentration-Time Weighted Average

PC-STEL: Permissible Concentration-Short Term Exposure Limit

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit

IDLH: Immediately Dangerous to Life or Health Concentrations



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