

Novo Nordisk A/S	DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET according to 91/155/EEC
	ACTIVELLA®

Trade name	Activella ® 0,5 mg/0,1 mg Activella ® 1 mg/0,5 mg	CAS.no	50-28-2 (Estradiol) 51-98-9 (Norethindrone acetate)
Chemical name	Estradiol, (E2) Norethindrone acetate (NETA)	EC-no.	
Novo Nordisk item no.	517511, 517401		
Company	Novo Nordisk Inc. 100 College Road West, Princeton, New Jersey 08540, USA.		
Emergency telephone no.	Tel.: + 1 609-987-5800		

COMPOSITION / INFORMATION ON CONTENTS			2
Hazardous ingredients	Concentration (w/w)		Classification
50-28-2 Estradiol	0,5 mg (1,0 mg)		T: R45,R60,R61,R48/23/24/25
51-98-9 Norethindrone acetate	0,1 mg (0,5 mg)		T: R46, R60,R61,R48/23/24/25

HAZARDS IDENTIFICATIONS		3
Potential Health Effects	Activella ® is a single tablet containing an estrogen, Estradiol and a progestin, Norethindrone acetate. Exposure to Activella ® may result in stimulating all female sexual characters. Exposure to Activella ® may cause irregular menstruation. Estradiol and Norethindrone acetate are known to cause birth defects in an unborn baby. Estradiol increases the risk of developing endometrial hyperplasia, a condition that may lead to cancer of the lining of the uterus. Using Norethindrone acetate with Estradiol lowers the risk of developing this condition.	
Inflammatory Properties	Activella ® is inflammable. By heating or when caught in a fire, Activella ® decomposes and toxic fumes are released.	

FIRST AID MEASURES		4
After swallowing	Rinse out mouth thoroughly with water and give plenty of water to drink. Do NOT provoke vomiting. Seek medical advice.	
Skin contact	Remove contaminated clothes and wash contaminated skin thoroughly with plenty of water for at least 15 minutes. Seek medical advice.	
Eyes	Rinse the eye immediately with plenty of water for at least 15 minutes with the eyelid held wide open. Seek medical advice.	
Inhalation	Go outside to breathe fresh air.	

PRECAUTIONS IN CASE OF FIRE		5
Do not stay in a dangerous zone without self-contained breathing apparatus. In order to avoid contact with skin, keep a safe distance and wear suitable protective clothing.		
Continued		

Novo Nordisk A/S	DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET according to 91/155/EEC
	ACTIVELLA®

ACCIDENTAL RELEASE MEASURES	6
------------------------------------	----------

Use personal protection means when removing the spillage. (See item 8). Absorb by means of absorbing material (e.g. sand or vermiculite) and send to proper destruction facilities. (See item 13). Clean up affected area.

HANDLING AND STORAGE	7
-----------------------------	----------

Activella ® must be kept in tightly closed original packaging in a well ventilated place.

EXPOSURE CONTROL / PERSONAL PROTECTION MEANS	8
---	----------

Limit value		Smell limit	-
-------------	--	-------------	---

Since the tablets are coated there is no risk in handling those, but if the tablets are crushed and dust is released, personal protection (breathing protection (filtertype P3) and disposable gloves) must be used. There must be easy access to a plentiful water supply and emergency or hand shower/eye rinsing bottle. Working clothes, which may be contaminated with Estradiol or Norethindrone acetate must be put in water-soluble plastic-bags before sending to the laundry.

PHYSICAL AND CHEMICAL CHARACTERISTICS	9
--	----------

Appearance	Filmcoated tablets	Water-solubility	Insoluble in water
Formula	(E2) C ₁₈ H ₂₄ O ₂ (NETA) C ₂₂ H ₂₈ O ₃	Molecular weight	(E2) 281,40 (NETA) 340,50
Density	No data	Freezing point	No data
Melting point	173-179° C	Flash point	Not applicable

STABILITY AND REACTIVE POWER	10
-------------------------------------	-----------

Activella ® is stable under normal circumstances,

TOXICOLOGICAL DATA	11
---------------------------	-----------

LD ₅₀ -value, oral (rat)	„	LD ₅₀ -value, dermal (rat)	- „
-------------------------------------	---	---------------------------------------	-----

Effects on long-term:	No	Under suspicion	Yes	Contradictory information	None
Carcinogenic			X		
Allergy (contact allergy)					X
Allergy (inhalation allergy)					X
Teratogenic			X		
Nerve damaging					X

Novo Nordisk A/S	DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET according to 91/155/EEC
	ACTIVELLA®

ENVIRONMENT INFORMATION	12
--------------------------------	-----------

Do not allow to enter waters, waste water, or soil.


DISPOSAL CONSIDERATIONS	13
--------------------------------	-----------

This material and its container must be disposed of as hazardous waste.
Spillage and waste are to be collected in proper receptacles and disposed at an approved site according to existence of local regulations regarding disposal.

INFORMATION ON TRANSPORT	14
---------------------------------	-----------

UN.no	-	Shipping name	-
ADR	Not dangerous goods	IMDG	Not dangerous goods
RID	Not dangerous goods	IATA	Not dangerous goods

REGULATORY INFORMATION	15
-------------------------------	-----------

Class of risks	Toxic (T)	Symbol:			
R-phrases:	R 45: May cause cancer R 46: May cause heritable genetic damage R 60: May impair fertility. R 61: May cause harm to the unborn child. R 48/23/24/25: Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.				
S-phrases:	S 53: Avoid exposure – obtain special instructions before use S 45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)				

No special regulations.

OTHER INFORMATION	16
--------------------------	-----------

No demand for special education, but persons handling Activella ® must be familiar with the instructions mentioned in these Material Safety Data Sheet.