One Step Multi-Drug Urine Test T-Cup (+Adulteration)

One Step Multi-Drug Urine Test T-Cup(+Adulteration) offers any combination from 2 to 15 drugs of abuse tests for 15 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP), Opiate (OPI 2000), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), Buprenorphine (BUP), Oxycodone (OXY), Propoxyphene (PPX). This drug test cup also provides one or more of the following adulterant controls_Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants, Bleach and Pyridinium Chlorochromate, to evaluate specimens for adulteration prior to drugs of abuse urine testing.

This package insert applies to all combinations of multi-drug tests panel with integrated cup. Therefore, some information on the performance characteristics of the product may not be relevant to your test. We refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test."

A rapid one step test for the qualitative detection of drug of abuse and their principal metabolites in human urine at specified cut off level. For healthcare professional use only. For in vitro diagnostic use.

INTENDED USE

One Step Multi-Drug Urine Test T-Cup(+Adulteration) is rapid urine screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

Test	Calibrator	Cut off (ng/ml)
Amphetamine	Amphetamine	1,000
Barbiturates	Secobarbital	300
Benzodiazepines	Oxazepam	300
Cocaine	Benzoylecgonine	300
Marijuana	Marijuana	50
Methadone	Methadone	300
Methamphetamine	Methamphetamine	1,000
Methylenedioxymethamphetamine	3,4-Methylenedioxymethamphetamine HCI(MDMA)	500
Morphine	Morphine	300
Opiate	Morphine	2000
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Notriptyline	1,000
Buprenorphine	Buprenorphine	10
Oxycodone	Oxycodone	100
Propoxyphene	Propoxyphene	300

This assay provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive.

PRINCIPLE

DRUG TESTS

One Step Multi-Drug Urine Test T-Cup(+Adulteration) is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dve conjugate binding sites.

When testing, the urine is absorbed upward by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When sample drug levels are at or above the target cutoff, the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored band in the test region indicating a potentially positive result.

When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

To serve as a procedure control, a colored line will appear on the control region (C), if the test has been performed properly.

One Step Multi-Drug Urine Test T-Cup(+Adulteration) results may be useful for assessing the integrity of the urine sample prior to drugs-of-abuse

testing. Test detects whether the sample contains adulterants including nitrite, glutaraldehyde, bleach, pyridinium chlorochromate and other oxidizing agents. Test can also assess whether the sample is possibly contaminated by acidic (vinegar) or basic (ammonia solution) adulterants as indicated by the pH test.

ADULTERATION CONTROL

In general, all seven tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with the corresponding pad on the color chart

Creatinine: Testing for sample dilution. In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

Glutaraldehyde: Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the glutaraldehyde reacts with an indicator to form a pink/purple color complex.

Nitrite: Testing for the presence of exogenous nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink-red/purple color.

Oxidants: Testing for presence of oxidizing reagents. In this reaction, a color indicator reacts with oxidants such as hydrogen peroxide, ferricyanide, persulfate, or pyridinium chloro- chromate to form a blue color complex. Other colors may indicate the presence of other oxidants.

pH: Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Specific Gravity: Testing for sample dilution. This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

Bleach: Testing for the presence of bleach in urine. In this test, the presence of bleach forms a blue-green color complex.

Pyridium Chlorochromate: Testing for the presence of chromate in urine. In this test, the presence of chromate forms a blue-green color complex.

ALCOHOL

Alcohol Test is intended for use to detect the presence of alcohol in urine greater than 0.04%.

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since the urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine was set at 0.04%. Normally, it will take at least 30 minutes for the alcohol to be detected in saliva, blood and urine after drinking

WARNINGS AND PRECAUTIONS

- . This kit is for external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiration date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.

STORAGE AND STABILITY

- Store at 4 °C ~ 30 °C up to the expiration date.
- . Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material provided

- One pouch containing a test T-cup and a desiccant.
- Package insert
- · A color chart for the aduteration strips

Material Required But Not Provided

Timer

SPECIMEN COLLECTION AND PREPARATION

- •Wash your hands with soap and warm water. Open the sealed pouch and remove the urine test T-cup.
- •The donors collect their urine samples. Open the cap of the cup and urinate directly into the test cup. The sample volume should be higher than

the minimum urine level. Re-cap the cup.

TEST PROCEDURE

- 1. After the urine has been collected, re-cap the cup and place the test T-cup on a flat surface.
- Start the timer.
- Peel the label from right to left and read the result. For the adulteration strip(s), compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results. If the results indicate adulteration, do not read the drug test results.
 - Note: All reagent areas may be read between 1 2 minutes. Changes in color after 2 minutes are of no diagnostic value.
- Read the results for the drugs at 5 minutes. Do not read after 5 minutes.



INTERPRATATION OF RESULTS

DRUGS

Positive (+)

A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

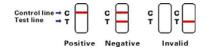
Negative (-)

A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Invalid

If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS

- 1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated
- Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
- 3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication
- 4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test
- 6. The test result does not distinguish between drugs of abuse and certain medicines.
- 7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

1200 (eighty of each drug) clinical urine specimens were analyzed by GC-MS and by each corresponding One Step Multi-Drug Urine Test T-Cup(+Adulteration). Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

AMP Viewer B +	Drug	Test Result		Less than half the cutoff concentratio n by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	%Agreement with GC/MS
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	Viewer C	+	0	0	10	30	100%
	Viewer C	-	29	11	0	0	100%
	\	+	0	1	10	28	95%
	Viewer A	-	10	19	2	0	97.50%
OXY	\	+	0	2	9	28	92.50%
UXY	Viewer B	-	10	18	3	0	95%
	Viewer C	+	0	0	8	28	90%
	viewei C	-	10	20	4	0	100%
	Viewer A	+	0	1	16	20	90%
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BUP	Viewer B	+	0	2	16	20	90%
ВОР	viewei B	-	10	18	4	0	95%
	Viewer C	+	0	0	16	20	90%
	viewei C	-	10	20	4	0	100%
	Viewer A	+	0	2	16	20	90%
	viewel A	-	18	10	4	0	95%
PPX	Viewer B	+	0	1	17	20	92.50%
PPX	viewerB	-	18	11	3	0	97.50%
	Viewer C	+	0	0	15	20	87.50%
	viewer C	-	18	12	5	0	100%

Precision and Sensitivity

To investigate the precision and sensitivity, for AMP, BAR, BZO, COC, THC, MTD, MET, MDMA, MOP, OPI, PCP and TCA, each drug samples were analyzed at the following concentrations: - 50%cutoff, - 25%cutoff, cutoff, +25%cutoff and + 50%cutoff. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots of the corresponding the drug of abuse test. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot of the corresponding the drug of abuse test.

For OXY, BUP and PPX, precision and sensitivity was assessed with three lots tested by three individuals over five consecutive days. In the study, seven separate normal urine samples were spiked with each drug to the following concentrations: Zero, -50% cutoff, -25% cutoff, cutoff, +50% cutoff and +100% cutoff. Level of the each drug for these samples was confirmed by GC/MS. Then each sample was divided into 75 aliquots that were further divided into 3 sets of 25 (one set for each lot). Each of the three operators tested 5 aliquots at each concentration for each lot per day. A total of 75 determinations by each operator, at each concentration, were made.

AMP(n	g/ml)	500	750	1000	1250	1500
Lot 1		90/0	78/12	32/58	14/76	0/90
Lot 2	(-/+)	90/0	78/12	32/58	14/76	0/90
Lot 3		90/0	78/12	32/58	14/76	0/90
BAR(n	g/ml)	150	225	300	375	450
Lot 1		90/0	79/11	42/48	18/72	0/90
Lot 2	(-/+)	90/0	79/11	42/48	18/72	0/90
Lot 3		90/0	79/11	42/48	18/72	0/90
BZO(n	g/ml)	150	225	300	375	450
Lot 1		90/0	79/11	41/49	9/81	0/90
Lot 2	(-/+)	90/0	79/11	41/49	11/79	0/90
Lot 3		90/0	80/10	41/49	11/79	0/90
COC(n	g/ml)	150	225	300	375	450
Lot 1		90/0	82/8	37/53	13/77	0/90
Lot 2	(-/+)	90/0	80/10	36/54	13/77	0/90
Lot 3	1	90/0	80/10	36/54	13/77	0/90

THC(n	g/ml)	25	38	50	63	75
Lot 1	Ĭ	90/0	76/14	43/47	12/78	0/90
Lot 2	(-/+)	90/0	76/14	43/47	12/78	0/90
Lot 3	1 ` ′	90/0	76/14	43/47	12/78	0/90
MTD(n	ıg/ml)	150	225	300	375	450
Lot 1		90/0	75/15	41/49	7/83	0/90
Lot 2	(-/+)	90/0	75/15	41/49	7/83	0/90
Lot 3		90/0	75/15	41/49	7/83	0/90
MET(n	ıg/ml)	500	750	1000	1250	1500
Lot 1		90/0	81/9	34/56	13/77	0/90
Lot 2	(-/+)	90/0	81/9	34/56	13/77	0/90
Lot 3		90/0	81/9	34/56	13/77	0/90
MDMA(ng/ml)	250	375	500	625	750
Lot 1		90/0	77/13	33/57	9/81	0/90
Lot 2	(-/+)	90/0	77/13	33/57	9/81	0/90
Lot 3		90/0	77/13	33/57	9/81	0/90
MOP(n	ng/ml)	150	225	300	375	450
Lot 1		90/0	77/13	28/62	8/82	0/90
Lot 2	(-/+)	90/0	77/13	28/62	8/82	0/90
Lot 3		90/0	77/13	28/62	6/84	0/90
OPI(n	g/ml)	1000	1500	2000	2500	3000
Lot 1		90/0	80/10	44/46	12/78	0/90
Lot 2	(-/+)	90/0	80/10	44/46	12/78	0/90
Lot 3		90/0	80/10	44/46	12/78	0/90
PCP(n	g/ml)	13	17	25	32	38
Lot 1		90/0	83/7	47/43	14/76	0/90
Lot 2	(-/+)	90/0	83/7	47/43	14/76	0/90
Lot 3		90/0	83/7	47/43	14/76	0/90
TCA(n	g/ml)	500	750	1000	1250	1500
Lot 1		90/0	78/12	41/49	13/77	0/90
Lot 2	(-/+)	90/0	78/12	41/49	13/77	0/90
Lot 3		90/0	78/12	41/49	13/77	0/90

OXY(ı	ng/ml)	0	5	75	100	125	150	200
Lot 1		75/0	75/0	63/12	10/65	3/72	0/75	0/75
Lot 2	(-/+)	75/0	75/0	64/11	11/64	4/71	0/75	0/75
Lot 3		75/0	75/0	63/12	9/66	2/73	0/75	0/75
BUP(ı	ng/ml)	0	5	7.5	10	12.5	15	20
Lot 1		75/0	75/0	62/13	9/66	4/71	0/75	0/75
Lot 2	(-/+)	75/0	75/0	63/12	8/67	3/72	0/75	0/75
Lot 3		75/0	75/0	61/14	9/66	2/73	0/75	0/75
PPX(r	ng/ml)	0	150	225	300	375	450	600
Lot 1		75/0	75/0	65/10	9/66	6/69	0/75	0/75
Lot 2	(-/+)	75/0	75/0	64/11	11/64	4/71	0/75	0/75
Lot 3		75/0	75/0	64/11	9/66	5/70	0/75	0/75

Analytical Specificity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components that are likely to be present in urine, All the components were added to drug-free normal human urine. These concentrations (ng/mL) below also represent the limits of detection for the specified drugs or metabolites.

Amphetamine		Methamphetamine	
d-Amphetamine	1,000	D(+)-Methamphetamine	1,000
d.1-Amphetamine	3,000	D-Amphetamine	50,000
1-Amphetamine	50,000	Chloroquine	50,000
(+/-) 3,4-methylenedioxyamphetamine	5,000	(+/-)-Ephedrine	50,000
Phentermine	3,000	(-)-Methamphetamine	25,000
d-methamphetamine	1,000	(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000

I-methamphetamine	3,000	b-Phenylethylamine	50,000
3,4-Methylenedioxyethylamphetamine	2,000	Trimethobenzamide	10,000
(MDE)			
(+/-)3,4-methylenedioxumethamphetamine (MDMA)	300	I-Methamphetamine	8,000
Barbiturates		3,4-Methylenedioxyamphetamine (MDA)	3,000
Secobarbital	300	3,4-Methylenedioxyethylamphetamine (MDE)	600
Amobarbital	300	I-Amphetamine	50,000
Alphenol	150	Methylenedioxymethamphetamine (MDMA)	
Aprobarbital	200	3,4-Methylenedioxymethamphetamine HCI(MDMA)	500
Butabarbital	75	3,4-Methylenedioxyamphetamine HCl	3,000
Butathal	100	3,4-Methylenedioxyethylamphetamine	300
Butalbital	2,500	D-Amphetamine	50,000
Cyclopentobarbital	600	L-Amphetamine	60,000
Pentobarbital	300	D-Methamphetamine	8,000
Phenobarbital	100	L-Methamphetamine	10,000
Benzodiazepines		Morphine	
Oxazepam	300	Morphine	300
Alprazolam	200	Codeine	300
α-Hydroxyalprazolam	1,500	Ethyl Morphine	300
Bromazepam	1,500	Hydrocodone	5,000
Chlordiazepoxide	1,500	Hydromorphone	5,000
Clonazepam HCI	800	Morphinie-3-β-d-glucuronide	1,000
Clobazam	100	Thebaine	30,000
Clonazepam	800	Heroin	300
Clorazepate dipotassium	200	σ-Monoacetylmorphine	400
Delorazepam	1,500	Oxycodone	30,000
Desalkylflurazepam Diazepam	400 200	Opiate 2000	2,000
Estazolam	2,500	Morphine Codeine	2,000
Flunitrazepam	400	Ethylmorphine	5,000
D,L-Lorazepam	1,500	Hydrocodone	12,500
Midazolam	12,500	Hydromorphine	5,000
Nitrazepam	100	Levorphanol	75,000
Norchlordiazepoxide	200	σ-Monoacetylmorphine	5,000
Nordiazepam	400	Morphine 3-β-D-glucuronide	2,000
Temazepam	100	Norcodeine	12,500
Trazolam	2,500	Normorphone	50,000
Cocaine		Oxycodone	25,000
Benzoylecgonine	300	Oxymorphine	25,000
Cocaine HCI	750	Procaine	150,000
Cocaethylene	12,500	Thebaine	100,000
Ecgonine	32,000	Heroin	2,000
Marijuana			
11-nor-∆9-THC-9-COOH	50	Phencyclidine	
11-nor-∆8-THC-9-COOH	30	Phencyclidine	25
11-hydroxy-∆9-Tetrahydrocannabinol	2,500	4-Hydroxyphencyclidine	12,500
∆8- Tetrahydrocannabinol	7,500	Phencyclidine morpholine	50
Δ9- Tetrahydrocannabinol	10,000	Methadone	
Cannabinol	10,000	Methadone	300
Cannabidiol	100,000	Doxylamine	50,000
Oxycodone	20.000	Tricyclic Antidepressants	1.000
Dihydrocodeine Codoine	20,000	Notriptyline	1,000
Codeine Hydromorphone	100,000	Nordoxepine Trimipramiine	1,000 3,000
Hydromorphone Morphine	>100,000	Amitriptyline	1,500
Norphine Acetylmorphine		Promazine	1,500
Acetylmorphine Buprenorphine	>100,000	Desipramine	200
Ethylmorphine	>100,000	Imipramine	400
Buprenorphine	r 100,000	Clomipramine	12,500
Buprenorphine Buprenorphine 3-D-Glucuronide	15	Doxepine	2,000

Norbuprenorphine	20	Maprotiline	2,000
Norbuprenorphine 3-D-Glucuronide	200	Promethazine	25,000
Propoxyphene			
d-Norpropoxyphene	300		

Cross-Reactivity

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with One Step Multi-Drug Urine Test T-Cup(+Adulteration) at a concentration of 100 µg/ml.

Non Crossing-Reacting Compounds

Acetophenetidin	Creatinine	Loperamide	Quinidine	Clonidine	Cortisone
Nalidixic acid	Deoxycorticosterone	Meprobamate	Quinine	Ketoprofen	D,L-Propanolol
Acetylsalicylic acid	Dextromethorphan	Methoxyphenamine	Ranitidine	Labetalol	L-Cotinine
Aminopyrine	Diclofenac	Nalidixic acid	Salicylic acid	Zomepirac	Prednisone
Amoxicillin	Diflunisal	Naloxone	Serotonin	Verapamil	Urine acid
Ampicillin	Digoxin	Naltrexone	Sulfamethazine	Isoxsuprine	D,L-Isoproterenol
L-Phenylephrine	Diphenhydramine	Naproxen	Sulindac	Phenylpropanolamine	Chlorquine
Apomorphine	L-ψ-Ephedrine	Niacinamide	Tetracycline	Cholesterol	3-Hydroxytyramine
Aspartame	Ecgonine methylester	Nifedipine	Tetrahydrocortisone,	D-Pseudoephedrine	Tyramine
Atropine	Ethyl-p-aminobenzoate	Norethindrone	3-Acetate	D,L-Tryptophan	L-Phenylephrine
Benzilic acid	β-Estradiol	D-Norpropoxyphene	Tetrahydrocortisone,	β-Phenylethylamine	Trimethoprim
Benzoic acid	Estrone-3-sulfate	Noscapine	(β-D-glucuronide)	Chlorpromazine	Phenelzine
Benzphetamine	Erythromycin	D,L-Octopamine	Tetrahydrozoline	D,L-Chlolrpheniramine	Perphenazine
Bilirubin	Fenoprofen	Oxalic acid	Thiamine	O-Hydroxyhippuric acid	Hydrocortisone
Deoxycorticosterone	Furosemide	Oxolinic acid	Thioridazine	Trifluoperazine	Chlorothiazide
Caffeine	Gentisic acid	Oxymetazoline	D,L-Tyrosine	Chloramphenicol	Triamterene
Hemoglobin	Papaverine	Tolbutamide	Hydrochlorothiazide	Penicillin-G	Hydralazine
Chloralhydrate	•		-		•

From the results above, it is clear that One Step Multi-Drug Urine Test T-Cup(+Adulteration) resists well against interference from these substances.

Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with each drug at 50% below and 50% above cutoff level. One Step Multi-Drug Urine Test T-Cup(+Adulteration) was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with morphine at 50% below and 50% above cutoff levels. One Step Multi-Drug Urine Test T-Cup(+Adulteration) was tested in duplicate. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

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MEANING OF SYMBOLS ON PACKAGE



Keep away from sunlight



Store between 4°C and 30°C



Keep dry



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