

OZO TOP

Safety considerations for the OZOTOP device





Introduction

Ozone is a disinfectant which has a very high efficiency compared to other disinfectants. The particularity of this disinfectant is that it has a very short “shelf life”, and therefore, can not be packaged, but must be produced in-situ.

This is the reason why ozone is not covered by the Pharma Directive (2001/83/CE) and the Biocide Directive (98/8/CE). As with any device to produce ozone, it is covered by the Medical Device Directive (93/42/CE).

As with any disinfectant, ozone is toxic, depending on the quantity.

Since there has been an increasing use of ozone in the food industry and water treatment, ozone toxicity has been extensively investigated from the environmental point of view to establish safety limits for workers.

Environmental limits are more stringent than clinical limits, because they take into account a long term effect, and that no benefits for the worker are expected.

Clinical limits for a drug would be expressed in terms of quantity of that drug, but environmental limits are expressed in terms of concentration in a volume.

Environmental limits (Concentration) could be converted to clinical limit (Dose):

- Concentration: ppm, or mg/m³ (for ozone, 1ppm = 2mg/m³)
- Dose = Concentration x Volume
- Volume = Flow Rate x Time.

Example:

Permissible exposure limit for worker (8-hour Time Weighted Average or TWA) is 0.1 ppm (0.2mg/m³).

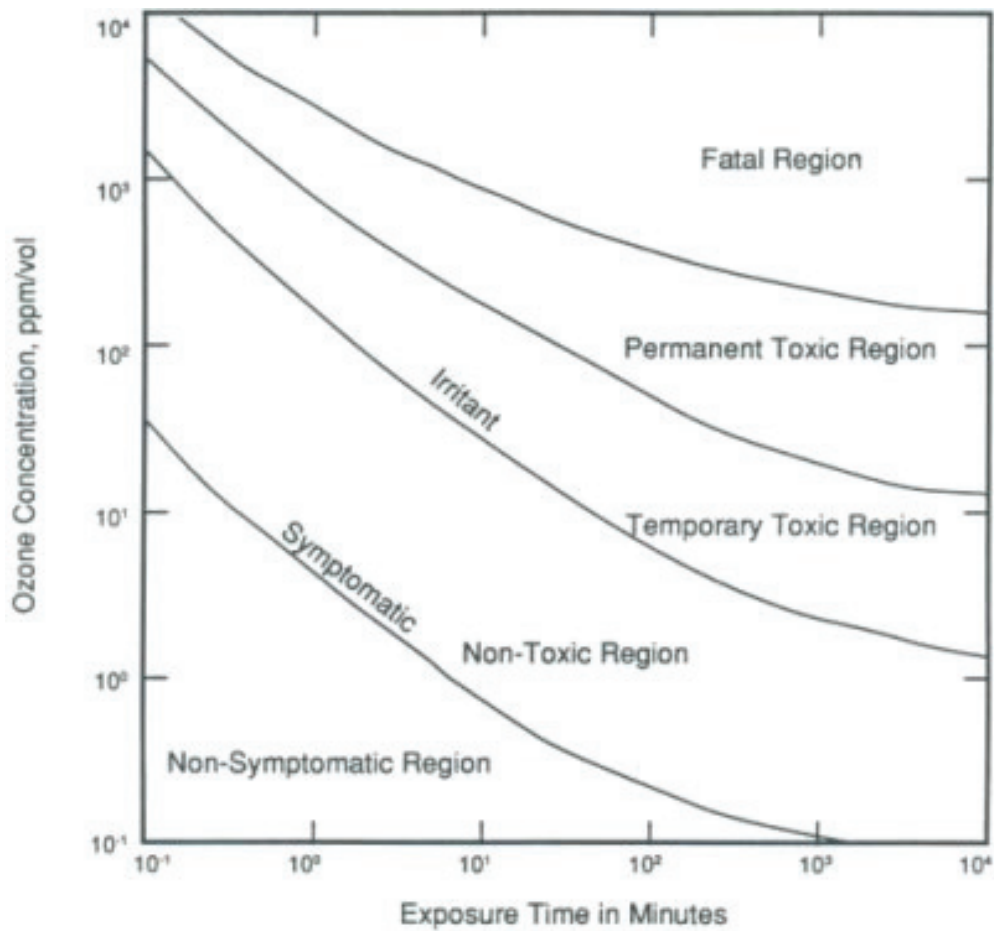
Total volume of air inhaled during this 8 hours: 0.5L * 30 x /min x 8 x 60 min = 7200 L (7.2 m³)

Thus the dose limit will be: 7.2 m³ * 0.2mg/m³ = **1.44 mg** of ozone.

Human tolerance level to ozone

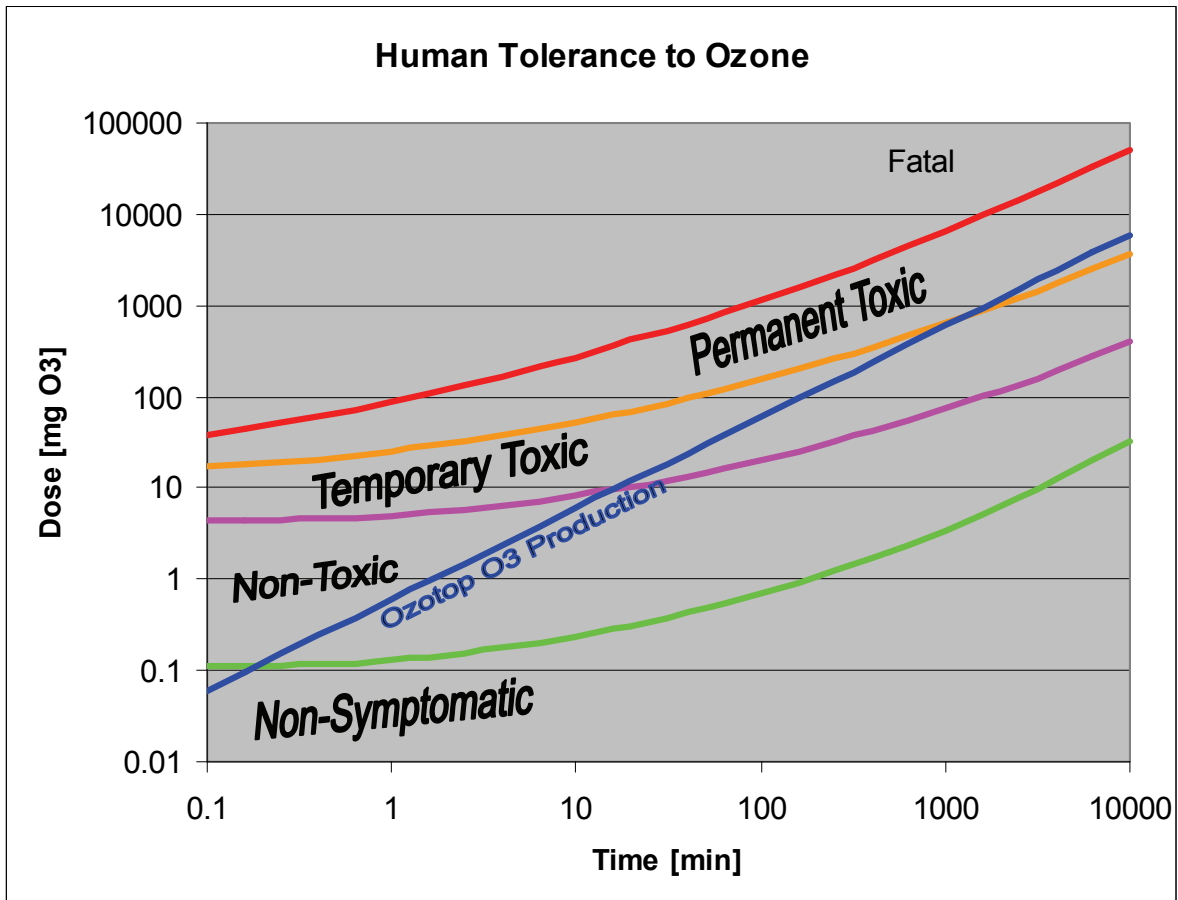
It is considered that the toxicity of ozone does not depend only of the quantity of ozone, but also of the time it is inhaled: the faster the inhalation, the lower the quantity administered.

The following diagram shows this relationship:



Since the volume inhaled is smaller as time decreases, the permitted concentration increases.

Same diagram converted to dose value (patient breathing at 0.5l x 30x / min) gives a better explanation from a clinical point of view:



The OZOTOP was designed not to reach the toxic region of this diagram should there be no suction applied at all.

Suction

The previous values show that the OZOTOP device is safe even in a condition where the patient inhales all the ozone produced by the device, which is not the normal case.

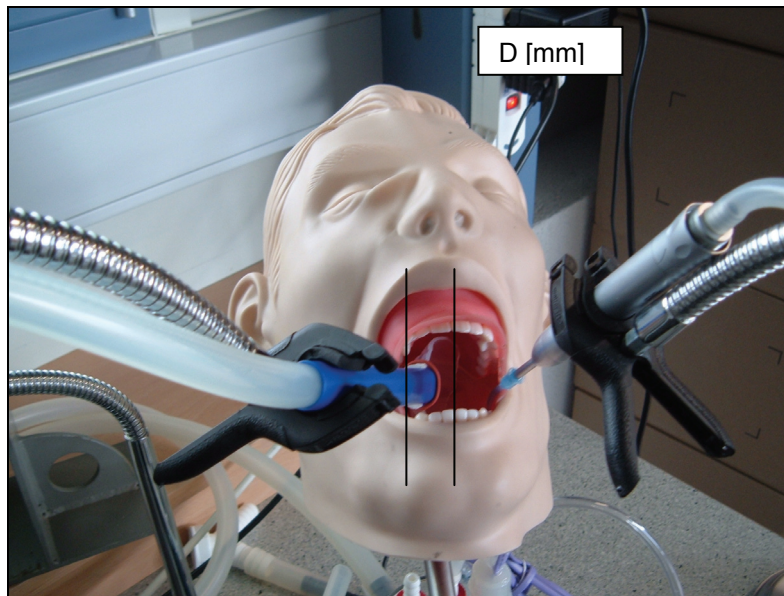
Ozone efficiency is obtained by the contact of the ozone flow within the treatment area. The residual ozone must be removed from the mouth with the suction.

In the mouth, the suction will have two effects:

1. Dilution: By adding air, the ozone will be diluted, thus decreasing the ozone concentration in the buccal cavity. A medium suction (ISO10637, Dental volume suction system) evacuates 90 l/min and the OZOTOP production reaches 140 ppm at 2 l/min after dilution, so the concentration level is $140 \text{ ppm} / 45 = 1.5 \text{ ppm}$

2. Aero dynamic barrier: With the position of the suction between the OZOTIP and the throat, an aero dynamic barrier, OZODAM, will be created to avoid the patient inhaling the ozone.

Suction: 50 l/min, patient: 10 l/min



Distance between suction and OZOTIP	ppm value measure in the throat (OZOTOP continuously producing ozone: 140ppm@2l/min rate)	
	Without OZODAM	With OZODAM
1 cm	0.06 ppm	0.05 ppm
2 cm	0.08 ppm	0.09 ppm
3 cm	0.23 ppm	0.17 ppm
Short Term Exposure Limit (15min) : 0.3 ppm		

The OZOTOP must be used with suction to remove the residual ozone.



OZOTOP Ozone production

Due to the analogy to environmental values, ozone generators are characterized with ppm value, which is not sufficient to define the dose. The OZOTOP is designed to produce a constant amount of ozone per time unit.

The OZOTOP ozone production is defined as 140 ppm @ 2 L/min, or
 $280 \text{ mg/m}^3 \times 0.002 \text{ m}^3 / \text{min} = 0.56 \text{ mg/min} = \mathbf{34 \text{ mg/hour}}$

This gives the following values for the different OZOTOP applications

Application	Dose of ozone	Ozotip Coro (1L/min)	Ozotip Perio (0.8 L/min)	Ozotip Endo (0.4 L/min)
6 sec	0.056 mg	280 ppm	350 ppm	700 ppm
12 sec	0.11 mg	280 ppm	350 ppm	700 ppm
18 sec	0.17 mg	280 ppm	350 ppm	700 ppm
24 sec	0.22 mg	280 ppm	350 ppm	700 ppm

Ozone efficiency:

Recent non-published in vitro tests with the OZOTOP in 500ul of suspended bacteria gave the following results:

Dose	S. Mutans destruction	A. Naeslundii destruction
0.17 mg O ₃	90 %	95 %
0.34 mg O ₃	99.9 %	99 %



Ozone level in dental office

To evaluate the ozone level reached with the OZOTOP, it is necessary to take into account the ozone production level of the OZOTOP and the ventilated air volume in the office.

The standard value for ventilation is 0.37 ACH (Air Change per Hour)

The standard volume of a Dental office is 30 m³.

Total volume of air during one day = 30 m³ x 0.37 ACH x 8 hours = 88 m³

Dose to reach the TWA value: 0.2 mg/m³ (0.1 ppm) x 88 m³ = **18 mg** of ozone

The maximum OZOTOP ozone production during a full day, applied to 10 patients/day,

Each patient treated with 5 x 24 sec application:

Total ozone production: 10 x 24 x 5 x 0.56 mg/min / 60 = **11 mg** of ozone.

The ozone produced by the OZOTOP is not sufficient to reach the 0.1 ppm limit value



REFERENCES STANDARDS AND REGULATIONS:

ORGANIZATION	STANDARD	REFERENCE
Mine Safety and Health Administration (MSHA) STANDARD - air	time-weighted average 0.1 ppm (0.2 mg/m ³)	DTLVS* 3,194,1971
Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (General Industry)	8 hour time-weighted average 0.1 ppm (0.2 mg/m ³)	CFRGBR 29,1910.1000,1994
Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (Construction)	8 hour time-weighted average 0.1 ppm (0.2 mg/m ³)	CFRGBR 29,1926.55,1994
Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (Shipyards)	8 hour time-weighted average 0.1 ppm (0.2 mg/m ³)	CFRGBR 29,1915.1000,1993
Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (Federal Contractors)	8 hour time-weighted average 0.1 ppm (0.2 mg/m ³)	CFRGBR 41,50-204.50,1994
Occupational Exposure Limit - ARAB Republic of Egypt	time-weighted average 0.1 ppm (0.02 mg/m ³), JAN1993	
Occupational Exposure Limit - AUSTRALIA	time-weighted average 0.1 ppm (0.2 mg/m ³), short term exposure limit 0.3 ppm, JAN1993	
Occupational Exposure Limit - AUSTRIA	MAK 0.1 ppm (0.2 mg/m ³), JAN1999	
Occupational Exposure Limit - BELGIUM	short term exposure limit 0.1 ppm (0.2 mg/m ³), JAN1993	
Occupational Exposure Limit - DENMARK	time-weighted average 0.1 ppm (0.2 mg/m ³), JAN1999	
Occupational Exposure Limit - FINLAND	time-weighted average 0.1 ppm (0.2 mg/m ³), short term exposure limit 0.3 ppm (0.6 mg/m ³), JAN1999	
Occupational Exposure Limit - FRANCE	VME 0.1 ppm (0.2 mg/m ³), VLE 0.2 ppm (0.4 mg/m ³), JAN1999	
Occupational Exposure Limit - GERMANY	MAK 0.1 ppm (0.2 mg/m ³), JAN1999	
Occupational Exposure Limit - HUNGARY	time-weighted average 0.2 mg/m ³ , short term exposure limit 0.4 mg/m ³ , JAN1993	
Occupational Exposure Limit - JAPAN	Occupational Exposure Limit 0.1 ppm (0.2 mg/m ³), JAN1999	
Occupational Exposure Limit - NORWAY	time-weighted average 0.1 ppm (0.2 mg/m ³), JAN1999	
Occupational Exposure Limit - THE PHILIPPINES	time-weighted average 0.1 ppm (0.2 mg/m ³), JAN1993	
Occupational Exposure Limit - POLAND	MAC(time-weighted average) 0.1 mg/m ³ , MAC(short term exposure limit) 0.6 mg/m ³ , JAN1999	
Occupational Exposure Limit - RUSSIA	short term exposure limit 0.1 mg/m ³ , JUN2003	
Occupational Exposure Limit - SWEDEN	NGV 0.1 ppm (0.2 mg/m ³), TGV 0.3 ppm (0.6 mg/m ³), JAN1999	
Occupational Exposure Limit - SWITZERLAND	MAK- week 0.1 ppm (0.2 mg/m ³), KZG- week 0.2 ppm (0.4 mg/m ³), JAN1999	
Occupational Exposure Limit - TURKEY	time-weighted average 0.1 ppm (0.2 mg/m ³), JAN1993	
Occupational Exposure Limit - UNITED KINGDOM	short term exposure limit 0.2 ppm (0.4 mg/m ³), SEP2000	
Occupational Exposure Limit IN ARGENTINA, BULGARIA, COLOMBIA, JORDAN, KOREA	American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value; Not classifiable as a human carcinogen	
Occupational Exposure Limit IN NEW ZEALAND, SINGAPORE, VIETNAM	American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value; Not classifiable as a human carcinogen	